PILOT STUDY OF A METHOD TO OBJECTIVELY MEASURE ASTHENOPIA SYMPTOMS

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Submitted to the faculty of the University Graduate School
in partial fulfillment of the requirements
for the degree
Master of Science
in the School of Optometry,
Indiana University
December 2019

Accepted by the Graduate Faculty, Indiana University, in partial fulfillment of the requirements for the degree of Master of Science.

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Acknowledgements

I would like to extend my gratitude to my committee: Drs. Pete Kollbaum, Arthur Bradley and Carolyn Begley. I would also like to thank Drs. Martin Rickert, Dawn Meyer, T. Rowan Candy, Ping Situ, Eva G. Hess, Basel Altoaimi, Meznah Saud Almutairi, Tao Liu, and Rhonda Bacher; as well as Jacob Maronge, Sarah Klingman-Cole, Andrew Huenink, Michael and Ellen Figueira, and the 2015-2016 CORL team, for their insight and expertise.

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Asthenopia is a commonly encountered clinical diagnosis in the pre-presbyopic demographic. With the increasing number of hours per day of computer and digital device usage in the population, its prevalence has been increasing. Asthenopia is defined to encompass a broad range of symptoms, which may be summarized in two categories: eyestrain due to accommodative or convergence dysfunction, or eyestrain as a manifestation of dry eye. While these categories are not mutually exclusive, treatment of asthenopia has historically been limited to the use of spectacle lenses to alleviate accommodative stress during near activities, and the isolated treatment of dry eye symptoms. New technologies in contact lens designs have been found to achieve asthenopia symptom relief based off subjective symptom surveys. The pilot study presented in this thesis presents a method of inducing asthenopia symptoms while objectively measuring the ocular response to the induction stimulus. This method may be performed while a contact lens is worn. Conceptually, this study was designed to explore a method that may be used in future research to investigate the in-vivo efficacy of anti-fatigue treatments (e.g. contact lenses) in an objective, rather than subjective, capacity. The results of this pilot project demonstrate the most promising method for future research involves testing with a small-font stimulus.

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Introduction

"My eyes feel like they're pulling." "I have headaches when I use my computer." "I get tired when I read."

One of the most common complaints from young adults heard by optometrists is of eyestrain. Better defined as asthenopia, it encompasses a broad range of symptoms that may include dry eyes, fatigue, eye strain or pain, headaches, blurry vision, and diplopia.[1] In a study of 609 18-39 year old adults taking part in a clinical response survey from the Indiana University School of Optometry's Clinical Optic Research Laboratory, over 25% of subjects reported eye fatigue (defined as "physical discomfort of their eyes after spending periods of time throughout the day in front of a digital screen") at least once per day, and 50% reported eye fatigue more than once per week.[2,3] These two figures correlate with my clinical experience, where approximately one third of my patients under the age of 35 present with symptoms related to asthenopia. The high prevalence of asthenopia is related to the changing landscape of digital device usage. As early as 1979, studies analyzing asthenopic symptoms of visual display unit operators were underway.[4] By 2011, 96% of working American adults were using new communications technologies, for example, the internet, as an "integral part of their job."[5] Today, computer screens, tablets, and smartphones are not just used in schools and the workplace, but for leisure activities as well. A 2014 Nielsen Report found that the average

[1] Sheedy JE, Hayes J, Engle J. Is All Asthenopia the Same? Optometry and Vision Science. 2003 Nov. 80(11): 732-739.
[2] Kollbaum P and Meyer D. Doctor, My Eyes…Are Tired! Review of Optometry. May 15, 2016. https://www.reviewofoptometry.com/article/doctor-my-eyes-are-tired. Accessed August 13, 2017.
[3] Meyer D, Huenink S, Rickert P, Kollbaum P, Chamberlain P. Symptoms associated with eye fatigue in soft contact lens wearers. Paper presented at: Annual Meeting of the American Academy of Optometry; October 2015; New Orleans, LA, USA.
[4] Stewart, TFM. Eyestrain and Visual Display Units: A Review. Displays. Apr 1979, 1(1): 17-24.
[5] US Department of Commerce. Fact Sheet: Digital Literacy. May 13, 2011. http://2010-2014.commerce.gov/news/fact-sheets/2011/05/13/fact-sheet-digital-literacy.html. Accessed: April 19, 2017.

American adult over age 18 spends an average of 11 hours per day on digital devices.[6] A 2016 Vision Council Survey reported 65% of Americans experience eyestrain symptoms when using digital devices.[7] Not everyone has difficulty with an increased use of technology during all hours of the day. But for those who suffer from asthenopia, maintaining a high level of achievement at work or school, and keeping an active social presence online can be difficult.

New technologies are in development to alleviate the symptoms of asthenopia for the pre-presbyopic population. In the spectacle market, anti-fatigue low-add progressive addition lenses are available, for example, the Hoya Sync and Essilor Eyezen. Studies have shown these spectacle lenses to be effective in the clinical management of asthenopia, by alleviating accommodative strain.[8] However, 2010 estimates from the CDC show that there are over 15 million contact lenses wearers under the age of 35 in the US alone.[9] It would behoove contact lens companies to answer this need with a product of their own. Anecdotal evidence states that the use of low-add simultaneous vision contact lens designs are effective in alleviating asthenopia symptoms. Recently, CooperVision released the Biofinity Energys contact lenses which have a "digital zone optical design" described as "multiple front-surface aspheric curves employed across the entire optical zone, which […] distribute power evenly to simulate more positive power in the center of the lens."[10] These contact lenses are marketed to "help with eye

[6] Brown, Molly. Nielsen Reports that the Average American Adult Spends 11 Hours Per Day on Gadgets. March 13, 2015. http://www.geekwire.com/2015/nielsen-reports-that-the-average-american-adult-spends-11-hours-per-day-on-gadgets/. Accessed: April 19, 2017.
[7] The Vision Council. Eyes Overexposed: The Digital Device Dilemma. 2016. https://visionimpactinstitute.org/wp-content/uploads/2016/03/2016EyeStrain_Report_WEB.pdf. Accessed October 1, 2017.
[8] Coronis, Timothy. Anti-Fatigue Lenses: Rx for Overworked Eyes. 20/20. June 2010. https://www.2020mag.com/article/anti-fatigue-lenses-rx-for-overworked-eyes. Accessed: April 19, 2017.
[9] Centers for Disease Control and Prevention. "Healthy Contact Lens Wear and Care." January 22, 2015. http://www.cdc.gov/contactlenses/fast-facts.html. Accessed: April 13, 2016.
[10] CooperVision. Digital Zone Optics. 2017. https://coopervision.com/practitioner/our-products/contact-lens-technology/digital-zone-optics. Accessed August 13, 2017.

tiredness caused by focusing on digital devices."[11] CooperVision provides studies that report that 80% of patients surveyed who use digital devices at least 4 hours per day at least 5 days per week and self-report symptoms of eye fatigue at least once per week had relief of eye tiredness with the Biofinity Energys contact lens.[12] However, these and other potential options of asthenopia-relieving contact lenses have not been tested in an objective setting; the current standard of measure is subjective, that of self-reported surveys.

Funded by the Clinical Optics Research Laboratory at Indiana University, the pilot study presented in this thesis evaluated four methods of artificially inducing asthenopia symptoms in a controlled laboratory environment. The experimental results may be useful in the development of a standardized objective method of measuring ocular fatigue with in vivo contact lenses. Future studies may be used to determine how effective a contact lens is at reducing the signs and symptoms of asthenopia, with a goal of providing additional evidence that low-add multifocal contact lenses are a valuable tool for the optometrist in the care of a pre-presbyopic patient suffering from asthenopia.

[11] CooperVision. Biofinity Energys. 2017. https://coopervision.com/practitioner/our-products/biofinity-family/biofinity-energys. Accessed August 13, 2017.
[12] Ibid.

Literature Review

The pilot study presented in this thesis explored four methods of inducing asthenopia in a controlled environment. Conceptually, the results of this study (determining the most promising method of reliably inducing and accurately measuring the induction of asthenopia) could then be repeated in a scenario with an optical aid designed to reduce the time to, and extent of, asthenopia symptoms. Therefore, knowledge of what is expected to cause asthenopia symptoms, as well as what is expected to alleviate those symptoms, must be well understood before a system may be designed to measure these criteria.

The following paragraphs review current knowledge of asthenopia, how it relates to accommodative disorders and dry eye, as well as reviewing clinical tests used to diagnose and the optical technologies used to treat the condition. Lastly, successful asthenopia induction procedures as presented in past literature will be reviewed.

Though it is a common ailment, asthenopia is not well understood. As pointed out nearly a decade apart by Watten and by Sheedy, the mechanism which results in the symptoms of asthenopia are not known. [13,14] Research has been ongoing since the early 1900s to determine if it is truly possible to fatigue the ciliary and extraocular musculature, or if the symptoms of "strain" or "visual fatigue" are actually interpretations of discomfort from other ocular structures.[15] Asthenopia is most likely the result of a wide variety of causative factors which present with remarkably similar symptomatology. The Mayo Clinic lists the following as examples which may induce asthenopia: looking at digital device screens, reading for long periods of time,

[13] Watten RG. Reinvention of Visual Fatigue: accumulation of scientific knowledge or neglect of scientific history? Ophthalmic and Physiological Optics. 1994 Oct. 14(4):428-432.
[14] Sheedy JE, et al. Is All Asthenopia the Same?
[15] Watten RG. Reinvention of Visual Fatigue.

driving or performing tasks that require focusing eyes for long periods of time, bright sunlight or glare, straining to see in dim illumination, exposure to dry moving air (e.g. from a fan, heater, or air conditioner), dry eyes, uncorrected refractive error, stress, and fatigue.[16] One can infer from this list that the primary causes of asthenopia involve two groups of ocular problems: (1) difficulty with near work, which in the pre-presbyopic demographic is often associated with accommodative dysfunction, and (2) dry eye related issues.

Accommodative disorders in pre-presbyopic individuals can be separated into five subgroups: accommodative insufficiency, accommodative infacility, ill-sustained accommodation, paralysis of accommodation, and accommodative spasm.[17] The first three types are relevant to this thesis, as symptoms of each may be alleviated with the proposed contact lens modality.

As defined by the American Optometric Association, accommodative insufficiency occurs "when the amplitude of accommodation is lower than expected for the patient's age, and is not due to sclerosis of the crystalline lens."[18] Symptoms of accommodative insufficiency are like those reported by emerging presbyopes: of straining and squinting to see clearly at a near working distance, or of simple near blur. Accommodative infacility occurs when "the accommodative system is slow in making a change, or when there is a considerable lag between the stimulus to accommodation and the accommodative response."[19] For example, patients with accommodative infacility report blurry vision at distance after periods of near work, and vice

[16] Mayo Foundation of Medical Education and Research. Disease and Conditions: Eyestrain. August 13, 2015. http://www.mayoclinic.org/diseases-conditions/eyestrain/basics/causes/con-20032649. Accessed April 13, 2016.
[17] Cooper JS, Burns CR, Cotter SA, Daum KM, Griffin JR, Scheiman MM. Optometric Clinical Practice Guideline: Care of the Patient with Accommodate and Vergence Dysfunction. American Optometric Association: St. Louis, MO. Approved March 20, 1998. Revised 2010. https://www.aoa.org/documents/optometrists/CPG-18.pdf. Accessed October 1, 2017.
[18] Ibid.
[19] Ibid.

versa. This can be particularly frustrating for students, who must repeatedly switch focus from near to distance when taking notes in class. Ill-sustained accommodation occurs when "the amplitude of accommodation is within the normal range, but fatigue occurs with repeated accommodative stimulation."[20] Patients suffering from this issue may not perceive asthenopic symptoms until having need of a short working distance for a long period of time. However, with many jobs and hobbies being performed on computers, smart phones, and tablets, ill-sustained accommodation can significantly impair a patient's productivity.

The final two categories of accommodative dysfunction are not as relevant to this project, as they require alternative interventions to treat. Paralysis of accommodation is fortunately rare, and presents with symptoms exactly corresponding to that of absolute presbyopia and a complete inability to accommodate.[21] Some causes are cycloplegic agents (such as those used in a diagnostic eye care setting) or as a sequela of trauma to the eye. Unless explained by either of those two, paralysis of accommodation is generally associated with a larger systemic problem, such as uveitis or toxicity.[22] Lastly, accommodative spasm is defined as "a spasm of the near reflex; the result of overstimulation of the parasympathetic nervous system."[23] It is often noted in a triad: accommodative excess, convergence excess, and mitotic pupils.

While asthenopia may be a multifaceted problem, "dry eyes" proves even more so. Dry eye symptoms also include a wide variety of presentation, including: foreign body sensation, grittiness, sandiness, blurred vision, pain (which may be sharp or a dull ache), and eyestrain.[24]

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[20] Ibid.
[21] Ibid.
[22] Walsh FB and Hoyt WF. Walsh and Hoyt's Clinical Neuro-ophthalmology. 6th ed. Ed Miller NR, Walsh FB, Hoyt WF. (Philadelphia: Lippincott Williams & Wilkins), 783-786.
[23] Cooper JS, et al. Optometric Clinical Practice Guideline.
[24] Mayo Foundation of Medical Education and Research. Disease and Conditions: Dry Eye. July 24, 2015. http://www.mayoclinic.org/diseases-conditions/dry-eyes/basics/symptoms/con-20024129. Accessed September 27, 2017.

When exploring the causes of dry eye, one must first consider the makeup of the tear film itself. Historically, the tear film was considered comprised of three layers: the outermost lipid layer, which protects the middle aqueous layer from evaporating, and the inner mucin layer which adheres the tears to the surface of the eye.[25] Each layer is produced by different glands in and around the eye (lipids from Meibomian glands, aqueous from lacrimal and accessory lacrimal glands, and mucin from the goblet cells of the conjunctiva). If any one of these glands malfunction, the tear film may be rendered unstable and inefficient. Additionally, the eyelids and nasolacrimal drainage system must work in concert to ensure proper in and outflow of tears across the surface of the eye. The 2017 TFOS DEWS II Tear Film Subcommittee revised the anatomy of the tear film to a two-layer organization: "a lipid layer overlying a muco-aqueous phase."[26] However, the two primary types of dry eye were not revised: aqueous deficient dry eye (wherein the aqueous layer is not produced in significant quantities) and evaporative dry eye (wherein the lipid layer does not prevent the aqueous layer from evaporating).[27]

Regardless of the type of dry eye, inflammation plays a significant role. In aqueous deficient dry eye, lymphocyte mediated upregulation of T-cells is found, suggestive of autoimmune inflammation.[28] Hyperosmolarity of the tear film, found both in aqueous deficient and evaporative dry eye, is a consequence of ocular surface stress which in turn activates pro-inflammatory cytokines.[29] Currently, it is not well understood if the inflammation is causative or

[25] Foster JB and Lee WB. The Tear Film: Anatomy, Structure, and Function. August 3, 2015. https://clinicalgate.com/the-tear-film-anatomy-structure-and-function. Accessed: September 27, 2017.
[26] Craig JP, Nelson JD, Azar DT, Belmonte C, Bron AJ, Chauhan SK, de Paiva CS, Gomes JAP, Hammitt KM, Jones L, Nichols JJ, Nichols KK, Novack GD, Stapleton FJ, Willcox MDP, Wolffsohn JS, Sullivan DA. TFOS DEWS II Report Executive Summary. The Ocular Surface. 2017 Oct. 15(4):802-812.
[27] Ibid.
[28] Hessen M, Akpek EK. Dry Eye: an Inflammatory Ocular Disease. Journal of Ophthalmic and Vision Research. 2014 Apr. 9(2): 240-250.
[29] Ibid.

a consequence of dry eyes, however, recognition of its presence has helped facilitate effective dry eye treatments (such as cyclosporine A and corticosteroids, in addition to the basic treatments of artificial tears and lid hygiene techniques).[30]

However, not all types of dry eye are intrinsic in origin, with causes relating to the very makeup of the tears as they are formed from the various glands. Dry eye symptoms may manifest from extrinsic forces, for instance, a fan or heater blowing dry air onto the face, or staring for long periods of time. It has been estimated that the average number of blinks per minute is 12-15, which reduces to 3-4 during prolonged computer work.[31] This may be a prime example of why dry eyes and asthenopia can be closely linked, particularly in patients who may otherwise have a normal tear film.

When optometrists receive a chief complaint of asthenopia, several tests in addition to the typical exam elements are warranted. To explore the patient's accommodative system, measurements in four categories of accommodative ability should be performed.[32] First, the amplitude of accommodation is measured via the push-up test. Accommodative facility is assessed via lens rock and distance rock tests. Relative accommodation is determined through the negative and positive relative accommodation measurements. Finally, lag of accommodation is measured via monocular estimate method retinoscopy, Nott retinoscopy, low neutral retinoscopy, or binocular crossed cylinder testing.

To determine the extent of dry eyes, the most common initial testing is to stain the tears with fluorescein dye, observe the cornea for punctate epithelial erosions (PEE, an early sign of

[30] Ibid.
[31] Orlando RG. Computer Eye Syndrome. Columbus Ophthalmology Associates. October 20, 2014. Available at: http://www.coavision.com/computer-eye-syndrome/. Accessed April 13, 2016.
[32] Goss DA. Ocular Accommodation, Convergence, and Fixation Disparity: A Manual of Clinical Analysis. 2nd ed. (Amsterdam: Elsevier, 1995), 135-149.

corneal epithelial compromise, which in the absence of a different inflammatory condition, are common with dry eyes[33]) and measure the tear-break-up-time (TBUT). A TBUT of under 10 seconds is considered indicative of dry eyes.[34] While TBUT has been shown adequate in assessing the extent of dry eyes, other testing is available to narrow down the root of the dry eye complaints. Assessment of tear quantity may be conducted via a simple measurement of the inferior tear meniscus (a measurement under 0.2 mm is indicative of dry eye)[35], or use of Shirmer Strips (a reading under 10 mm after 5 minutes is consistent with dry eye) or Phenyl Red Thread (if under 10 mm after 15 seconds).[36] Tear quality may be determined with tools such as the TearLab, which measures tear osmolarity (in mOsm/L) with loss of tear homeostasis indicated by a reading over 300 mOsm/L or a difference between readings in each eye over 8 mOsm/L.[37] Another option is the Inflammadry, which detects levels of MMP-9, an inflammatory marker found on the conjunctiva, common to dry eye sufferers.[38]

However, in contact lens wearing patients, the tear film is already disrupted by the thin layer of synthetic material covering the cornea.[39] Indeed, contact lens induced dry eye (CLIDE) is a common complaint among contact lens wearers. In a 2005 report, contact lens wearers were ten times more likely to have dry eye symptoms than those requiring no refractive correction,

[33] McKenzie M and Whitley W. A Closer Look at Corneal Inflammation. Review of Cornea and Contact Lenses. November 15, 2012. Available at: http://www.reviewofcontactlenses.com/content/d/irregular_cornea/c/37560/. Accessed April 13, 2016.
[34] Johnson ME and Murphy PJ. The Effect of Instilled Fluorescein Solution Volume on the Values and Repeatability of TBUT Measurements. Cornea. 2005 Oct. 24(7): 811-817.
[35] Doughty MJ, Lauguzzaman M, Oblak E, Button N. The tear (lacrimal) meniscus height in human eyes: a useful clinical measure or an unusable variable sign? Contact Lens and Anterior Eye. 2002 Jun. 25(2): 57-65.
[36] Vashisht S and Singh S. Evaluation of Phenyl Red Thread Test versus Shirmer Test in Dry Eyes: A Comparative Study. International Journal of Applied Basic Medical Research. 2011 Jan-Jun. 1(1): 40–42.
[37] TearLab. How Tear Lab Works. 2016. Available at: http://www.tearlab.com/. Accessed April 13, 2016.
[38] RPS. Identify Dry Eye with Inflammadry. 2016. Available at: https://www.rpsdetectors.com/in/products/identify-dry-eye-with-inflammadry/. Accessed April 13, 2016.
[39] Landers RA. Effect of Contact Lenses on Tear Film Integrity. American Academy of Optometry Abstract. October 25, 2007. Available at: http://www.aaopt.org/effect-contact-lenses-tear-film-integrity. Accessed April 13, 2016.

and five times more likely than spectacle wearers.[40] Practitioners have become creative over years of treating CLIDE patients who desire to continue wearing contact lenses. For instance, increased intake of omega-3 fatty acids (which are natural anti-inflammatories), treatment of subclinical Meibomian gland disease (such the lid hygiene techniques of warm compresses and lid scrubs, as well as off-label use of oral doxycycline or topical azithromycin), use of topical lubrication (artificial tears such as Blink Contacts, Opti-Free Rewetting Drops and Refresh Contacts are formulated specifically for use concurrent with contact lens wear), treatment of underlying allergic conditions (with topical or systemic antihistamines), use of topical anti-inflammatory agents (such as cyclosporine A or corticosteroids, previously mentioned as treatments of the inflammatory component of all dry eyes), and finally, a re-evaluation of the contact lenses themselves.[41]

Contact lens manufacturers have taken note of the issue. For example, CooperVision Proclear lenses carry the FDA distinction of providing "improved comfort for contact lens wearers who experience mild discomfort or symptoms relating to dryness during lens wear."[42] Though no other contact lens brand carries a similar FDA approval, several other lens options are recommended to alleviate some dry eye symptoms. Daily disposable lenses, such as the Alcon Dailies Total 1 with its water gradient technology are designed specifically with hydration in mind.[43] X-Cel's 2 week replacement lens Extreme H_2O 59% is marketed as the "problem solver for dryness," particularly in computer users who experience "reduced visual acuity after 6-8

[40] Nichols JJ, Ziegler C, Mitchell Gl, Nichols KK. Self-reported dry eye disease across refractive modalities. Investigative Ophthalmology and Visual Science. 2005 Jun. 46(6):1911-4.
[41] Krohn J. How to Address CLIDE. Review of Cornea and Contact Lenses. March 19, 2012. Available at: http://www.reviewofcontactlenses.com/content/c/33099/. Accessed April 13, 2016.
[42] CooperVision. Proclear Family. 2016. Available at: http://coopervision.com/contact-lenses/proclear-family. Accessed April 13, 2016.
[43] Alcon. Dailies Total 1. 2014. Available at: http://www.dailies.com/products/dailies-total1.shtml. Accessed April 13, 2016.

hours of wear due to lens instability."[44] Bausch+Lomb's Ultra with MoistureSeal technology is advertised to "feel moist and comfortable even after long hours on [your] digital devices."[45]

Often the primary cause(s) of the asthenopic symptoms are subclinical. They may be a manifestation of compounding factors, or perhaps by a mechanism we do not yet know. Additionally, the combination of mild accommodative disability and dry eyes are not mutually exclusive; for instance, a patient straining their accommodative system is also likely to stare, thus blinking more infrequently. Nevertheless, the treatment options available do not necessarily cure the underlying problem, but may help to alleviate the symptoms enough that eyestrain is no longer noticed by the patient. Unfortunately, as common as asthenopia is, there are not many tools available for the optometrist to prescribe. Most doctors will start with simple recommendations such as the 20/20/20 rule (when performing a task that results with eyestrain symptoms, every 20 minutes take 20 seconds to look at least 20 feet away), or, if dry eyes appear to be concurrent, the use of artificial tears 2 to 3 times per day.

However, if a true accommodative problem is at fault, specific and targeted treatment is warranted. Of the three highlighted accommodative disorders, accommodative infacility is the only one in which vision therapy is considered a first line treatment.[46] Accommodative insufficiency and ill-sustained accommodation are best relieved with a plus add at near.[47] Currently, this is achieved with bifocal spectacles. Nearly 10 years ago, anti-fatigue progressive

[44] X-CEL. Extreme H_2O 59% Sphere: the Problem Solving Lens for Patients Who Experience Dryness and Discomfort. Available at: https://www.hydrogelvision.com/aspx/lenses/default.aspx?linkid=7. Accessed April 13, 2016.
[45] Bausch + Lomb. Bausch+Lomb ULTRA contact lenses with MoistureSeal technology. 2016. Available at: http://www.bausch.com/our-products/contact-lenses/lenses-for-nearsighted-farsighted/bausch-lomb-ultra-contact-lenses#.Vw56rZXmrX4. Accessed April 13, 2016.
[46] Goss DA. Ocular Accommodation, Convergence, and Fixation Disparity: A Manual of Clinical Analysis, 150-163.
[47] Ibid, 135-149.

spectacle lenses were introduced specifically for this young demographic of asthenopia sufferers. Designs vary among manufacturers, but the concept is the same: a low-add progressive provides a small boost of add power for near viewing, which should alleviate asthenopia symptoms due to accommodative dysfunction. Add powers range from +0.40 (Essilor Eyezen 1), +0.53 (Hoya Sync 5), +0.60 (Essilor Eyezen 2), +0.75 (KODAK Anti-Fatigue), +0.85 (Essilor Eyezen 3) to +0.88 (Hoya Sync 8).

New technologies in contact lenses have led to advancements in multifocal contact lens options. In soft contact lenses, simultaneous vision lens designs (biconcentric, zonal, or aspheric) are most prevalent.[48,49] The concept behind simultaneous vision is to allow improved binocularity at all distances over the alternative of monovision, wherein the non-dominant eye is focused for a near point target, separating the two eyes from observing distance and near visual stimuli together. Biconcentric lens designs have two distinct zones, with the central zone being corrected for either distance or near.[50] These are most often used in a "modified monovision" setting (one eye has a center distance lens, the other, center near), achieving improved stereovision over a traditional monovision.[51] However, the expectation is that a pupil is large enough to accommodate both optical zones, providing vision at two distances in the same lens. In patients with small pupils, this lens effectively becomes a monofocal lens and the benefit of the simultaneous vision lens design is lost.[52] The most common zonal design, also called the multi-zone concentric design, is a 5-zone lens, starting with a 2 mm diameter distance focus in

[48] Plainis S, Atchison DA, Charman WN. Power Profiles of Multifocal Contact Lenses and Their Interpretation. Optometry and Vision Science. 2013 Oct. 90(10): 1066-1077.
[49] Toshida H, Takahashi K, Sado K, Kanai A, Murakami A. Bifocal Contact Lenses: History, Types, Characteristics, and Actual State and Problems. Clinical Ophthalmology. 2008 Dec. 2(4): 869-877.
[50] Pérez-Prados R, Piñero DP, Pérez-Cambrodí RJ, Madrid-Costa D. Soft Multifocal Simultaneous Image Contact Lenses: A Review. Clinical and Experimental Optometry. 2017 Mar. 100(2): 107-127.
[51] Efron N. (Ed). Contact Lens Practice. 3rd ed. (Amsterdam: Elsevier, 2018), 216-219.
[52] Ibid.

the center, then alternating near and distance focus in rings extending peripherally.[53] Both biconcentric and multi-zone concentric designs may provide binocular vision at distance and near; however, they do not provide an intermediate range of clear vision.

Aspheric designs are the only simultaneous vision design contact lenses which provide a full-range of vision. Aspheric contact lens designs are achieved by utilizing spherical aberration, inducing add power as a function of eccentricity from the center of the lens.[54] Higher add powers require an increased amount of spherical aberration. However, the cost of this design is of mildly decreased focus at all distances due to the presence of the aberrations.[55] These multifocal lenses are generally marketed to the presbyopic patient, as an alternative to progressive addition spectacle lenses, or bifocals. By inference, it does make sense that a low add multifocal contact lens would be a reasonable alternative to anti-fatigue spectacle lenses. The Biofinity Energys falls into the category of a low-add aspheric simultaneous vision contact lens design.[56] With limited amounts of spherical aberration (due to the low power of the lens), high quality vision at all distances should be preserved, while a benefit of a low add power should decrease the accommodative demand required during near tasks. In theory, this lens should provide the same benefit as the anti-fatigue design spectacle lenses.

The precedent for exploring asthenopia in an experimental setting was set by Sheedy in his 2003 article "Is all Asthenopia the Same?" In his study, eight induction testing conditions were explored, including lens flipper, close working distance, small font, dry eye, flickering

[53] Eiden SB. Multiple Multifocal Lenses Make It Easy. Review of Optometry. December 15, 2008. Available at: https://www.reviewofoptometry.com/article/multiple-multifocal-lenses-make-it-easy. Accessed September 27, 2017.
[54] Pérez-Prados R, et al. Soft Multifocal Simultaneous Image Contact Lenses: A Review.
[55] Ibid.
[56] CooperVision. Digital Zone Optics.

light, glare, mixed astigmatism, and upward gaze conditions.[57] The lens flipper condition activated accommodative stress, while the close working distance condition isolated convergence stress by inducing convergence while eliminating the accommodative demand of the task.[58] The small font condition was intended to require intense focus and concentration on the stimulus item; a behavior that is known to result with asthenopia symptoms.[59] The dry eye condition exploited the known correlation between asthenopia and dry eye,[60] while the flickering light, glare, mixed astigmatism, and upward gaze conditions required an intense focus similar to the small font condition. All eight induction testing conditions were found to induce asthenopia. Exploration of participants' survey results describing symptoms associated with each induction method showed that asthenopia may be divided into two categories: internal asthenopia related to stress of the accommodative and/or binocular vision systems (ache, strain, headache) and external asthenopia related to stress of ocular surface structures (burning, irritation, tearing, dryness).[61] Internal symptoms were found to be induced by the close viewing distance, lens flipper, and mixed astigmatism conditions.[62] External symptoms were induced by dry eye, glare, up-gaze, small font, and flickering light conditions.[63]

Further exploration on parsing differences between various experimental asthenopia induction techniques has focused on the act of squinting, with the conclusion that participants squint during testing when the action would feasibly help clear the image.[64] That is, the pinhole

[57] Sheedy JE, et al. Is All Asthenopia the Same?
[58] Gowrisankaran S, Sheedy JE, Hayes JR. Eyelid Squint Response to Asthenopia-Inducing Conditions. Optometry and Vision Science. 2007 Jul. 84(7): 611-619.
[59] Mayo Foundation of Medical Education and Research. Disease and Conditions: Eyestrain.
[60] Ibid.
[61] Sheedy JE, et al. Is All Asthenopia the Same?
[62] Ibid.
[63] Ibid.
[64] Gowrisankaran S, et al. Eyelid Squint Response to Asthenopia-Inducing Conditions.

effect resultant from the act of squinting works best for causative factors such as uncorrected refractive error or glare, but not for small font, or accommodative and convergence stresses.

Lastly, it is known that a correlation exists between decreased blink rate and asthenopia.[65,66,67] Comparison of baseline blink rate to the decreased blink rate seen when a participant begins to experience asthenopia may provide an additional objective measure of asthenopia induction. It is likely that decreased blink rate is most associated with the external asthenopia symptoms (as defined by Sheedy),[68] as decreased blink rate may be related to dry eye.

The induction tests selected for this pilot study were the lens flipper, close working distance, and small font conditions. These were chosen to replicate the successful asthenopia induction techniques referenced above, and further parsed on the expected capability of the COAS aberrometer to capture data on defocus and pupil size during the induction task.[69] The measurement of defocus provides the most compelling data to suggest whether asthenopia is induced, and, in the future, may be used to show if a participant is utilizing an add boost in a contact lens. As it is expected that as a participant fatigues during testing, tonic accommodation is reduced; therefore, via comparison to baseline testing, the defocus measurement may provide objective proof that asthenopia was (or was not) induced. [70] Data on pupil size may also be collected by the COAS; its usefulness related to the involuntary triad of accommodation, convergence, and miosis. The theory is that pupil size data may be used to infer additional

[65] Patel S, Henderson R, Bradley L, Galloway B, Hunter L. Effect of visual display unit use on blink rate and tear stability. Optometry and Vision Science. 1991 Nov. 68(11):888-892.
[66] Kollbaum P and Meyer D. Doctor, My Eyes…Are Tired!
[67] Gowrisankaran S, Nahar NK, Hayes J, Sheedy JE. Asthenopia and blink rate under visual and cognitive loads. Optometry and Vision Science. 2012 Jan. 89(1):97-104.
[68] Sheedy JE, et al. Is All Asthenopia the Same?
[69] Neal D and Voss LB. Wavefront Sciences Optics and Instrumentation Complete Ophthalmic Analysis System User's Manual Version 1.44.07. January 10, 2006.
[70] Hasebe S, Graf EW, Schor CM. Fatigue Reduces Tonic Accommodation. Ophthalmic and Physiologic Optics. 2001 Mar. 21(2):151-60.

information on accommodation and convergence. However, the relationship between diopters of accommodation, amount of vergence and pupil size is not necessarily linear or consistent.[71,72] With such variability, this measurement will not be investigated in this thesis.

Utilizing knowledge gained from past studies on the topic, the purpose of this thesis is to create a method of objectively measuring accommodative status (via objective measurements of accommodative demand and response) and tear film stability (via objective measurements of dry eye) with in vivo contact lenses. This method may then be applied to determine if a contact lens marketed to treat asthenopia is effective at relieving accommodative strain and moderating dry eye.

[71] Kasthurirangan S and Glasser A. Age Related Changes in the Characteristics of the Near Pupil Response. Vision Research. 2006 Apr. 46(8-9):1393-1403.
[72] Ripps H, Chin NB, Siegel IM, Breinin GM. The effect of pupil size on accommodation, convergence and the ACA ratio. Investigative Ophthalmology. 1962 Feb. 1(1): 127-135.

Methodology

The study design was created to pilot test a system by which asthenopia could be reproducibly induced and monitored in a research setting.

Four induction techniques were selected, to explore which provided the most efficient and repeatable induction of asthenopia that could be monitored in real-time by the COAS aberrometer. Multiple baseline tests were captured, to allow for analysis within each subject as well as between subjects. Testing of subjective participant responses were procured, to allow assessment of correlation between objective and subjective testing results. Finally, measures of possible confounding factors, such as dry eye, were evaluated throughout the testing scenarios.

This experiment was performed in two parts: the first visit was a screening-visit to determine a participant's candidacy for the second, study-visit. Case report forms for the two visits may be found in Appendix 1.

Each participant consented to participate in the study per a protocol approved by the Indiana University Institutional Review Board. The participants were recruited from the student body at the Indiana University School of Optometry, selected via the following criteria:

Inclusion Criteria:

- Has received an oculo-visual examination in the last two years
- Is between 18 and 35 years of age with full legal capacity to volunteer
- Has read and understood the informed consent letter
- Is willing and able to follow instructions and maintain the appointment schedule
- Is correctable to a visual acuity of 20/25 or better (in each eye) with their habitual correction or 20/20 best corrected

- Currently wears soft contact lenses between -0.50 D and -6.00 D
- Has a spherical Contact Lens Rx between -0.50 and -6.00 and spectacle cylinder $\leq$-0.75
- Has not worn lenses for at least 12 hours before the examination
- Is symptomatic of eyestrain; self-reports symptoms at a frequency equal to or greater than 1x/week (as determined by Eye Fatigue Experiences Questionnaire, see Appendix 2)

Exclusion Criteria:

- Has never worn contact lenses before
- Has any systemic disease affecting ocular health
- Is using any systemic or topical medications that will affect ocular health
- Has any ocular pathology or anomaly that would affect the wearing of the contact lenses
- Has any dry eye signs and/or symptoms (CLDEQ-8 total of $\geq$12, see Appendix 2; Non-invasive TBUT<10 seconds, confirmed after 3 measurements averaged together)
- Has persistent, clinically significant corneal or conjunctival staining using sodium fluorescein dye
- Is aphakic
- Has uncorrected anisometropia of $\geq$2.00
- Has undergone corneal refractive surgery
- Is participating in any other type of eye related clinical or research study

Each participant read and signed an Informed Consent Statement, an Authorization for the Release of Health Information for Research form, and an agreement to be compensated at a rate of $40.00/hour rounded to the nearest 0.25 hour for the two visits required to complete participation in the study.

The primary objective of the screening-visit was to ensure that study participants did not have any pre-existing medical, binocular vision, dry eye or refractive problems that would confound the data collected in the study-visit. This was confirmed by careful measurement of the participant's refractive state before and after cycloplegia, by a thorough anterior segment ocular health examination, and by evaluation of the binocular vision system. Baseline results on the non-invasive tear break up time and Eye Fatigue Rating Questionnaire (EFRQ, see Appendix 2) were also obtained, which could then be compared to the same results collected at the study-visit.

Materials required for the screening-visit included:

- Ocular examination lane with typical equipment: slit lamp for biomicroscopy, 1% Tropicamide eye drops, sodium fluorescein ophthalmic strips, Phoropter for refractive and binocular vision testing, auto-refractor/auto-keratometer, retinoscope, PD stick, visual acuity chart (traditional Snellen letters on projector screen, and Sloan optotypes on LogMAR high intensity/high contrast acuity chart at 4m and 40cm), photometer to measure room luminance/illuminance in cd/m^2
- Medmont E300 Corneal Topographer to perform non-invasive tear break up time measurements

The study-visit design was to place the participant into scenarios that would induce symptoms of asthenopia (as defined by the EFRQ)[73,74] while objectively measuring via the COAS aberrometer the defocus and pupil size of the participant's right eye.

[73] Meyer D, et al. Symptoms associated with eye fatigue in soft contact lens wearers.
[74] Kollbaum PS, Meyer D, Huenink S, Rickert M, Chamberlain P, Hall L. Digital Device User Survey of Eye Fatigue. Paper presented at: Association for Research in Vision and Ophthalmology; May 2016; Seattle, WA, USA.

Materials required for the study-visit included:

- Biofinity contact lenses, see Table 1:

Table 1

Biofinity Contact Lens Specifications

Manufacturer	CooperVision
Material	Comfilcon A
Base Curve (mm)	8.6
Diameter (mm)	14.0
Power (D)	-0.50 to -6.00
Add	n/a
Wear regimen	Daily Wear
Spherical Aberration (μm)[75]	-0.31

Table 2

Contact Lens Powers Utilized

Participant	Right eye (D)	Left eye (D)
01	-2.50	-2.25
03	-4.25	-4.50
05	-1.25	-2.00
06	-2.00	-1.75
07	-2.25	-2.00
08	-2.75	-2.75
09	-4.25	-4.25
10	-1.50	-2.00

[75] Altoaimi BH, Almutairi MS, Kollbaum P, Bradley A. Accommodative Behavior of Eyes Wearing Aspheric Single Vision Contact Lenses. Optometry and Vision Science. 2017 Oct. 94(10): 971-980.

- Optics table with affixed ruler and mount to keep stimulus items at chosen test distances, with bite bar stabilization to hold all participants and equipment steady in testing configuration
- Wavefront Sciences COAS Aberrometer to provide real-time measurements of accommodative status during testing scenarios[76]
- GoPro Hero 4 silver edition camera with custom mount to place camera at a 22 cm working distance from the participant's pupil plane
- Equipment for testing stimuli: microdisplay for baseline testing, iPhone 4, MacBook Pro laptop with external Apple Magic TrackPad
- Software for testing stimuli: calibrated Snellen "E" to provide 2M visual stimulus at a distance target of 200 cm for baseline distance testing (Figure 1), Mahjong Solitaire Epic HD v2.2.1 Application by Kristanix Games as testing stimuli at near (tiles set to letters in the English alphabet and numbers rather than characters or symbols, for examples see Figure 2), TeamViewer Remote Control Application to mirror the Mahjong game screen onto the iPhone, while being controlled by the participant on the MacBook Pro via the external Apple Magic TrackPad

[76] Neal D and Voss LB. Wavefront Sciences Optics and Instrumentation Complete Ophthalmic Analysis System User's Manual.

Figure 1

Snellen Letter E Calibrated for Microdisplay

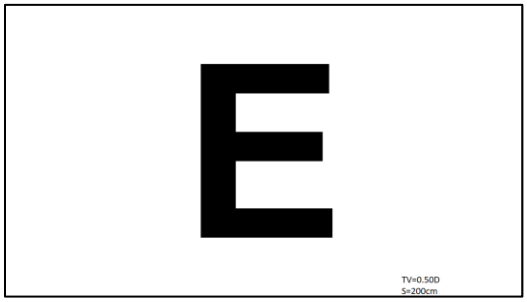


Figure 2

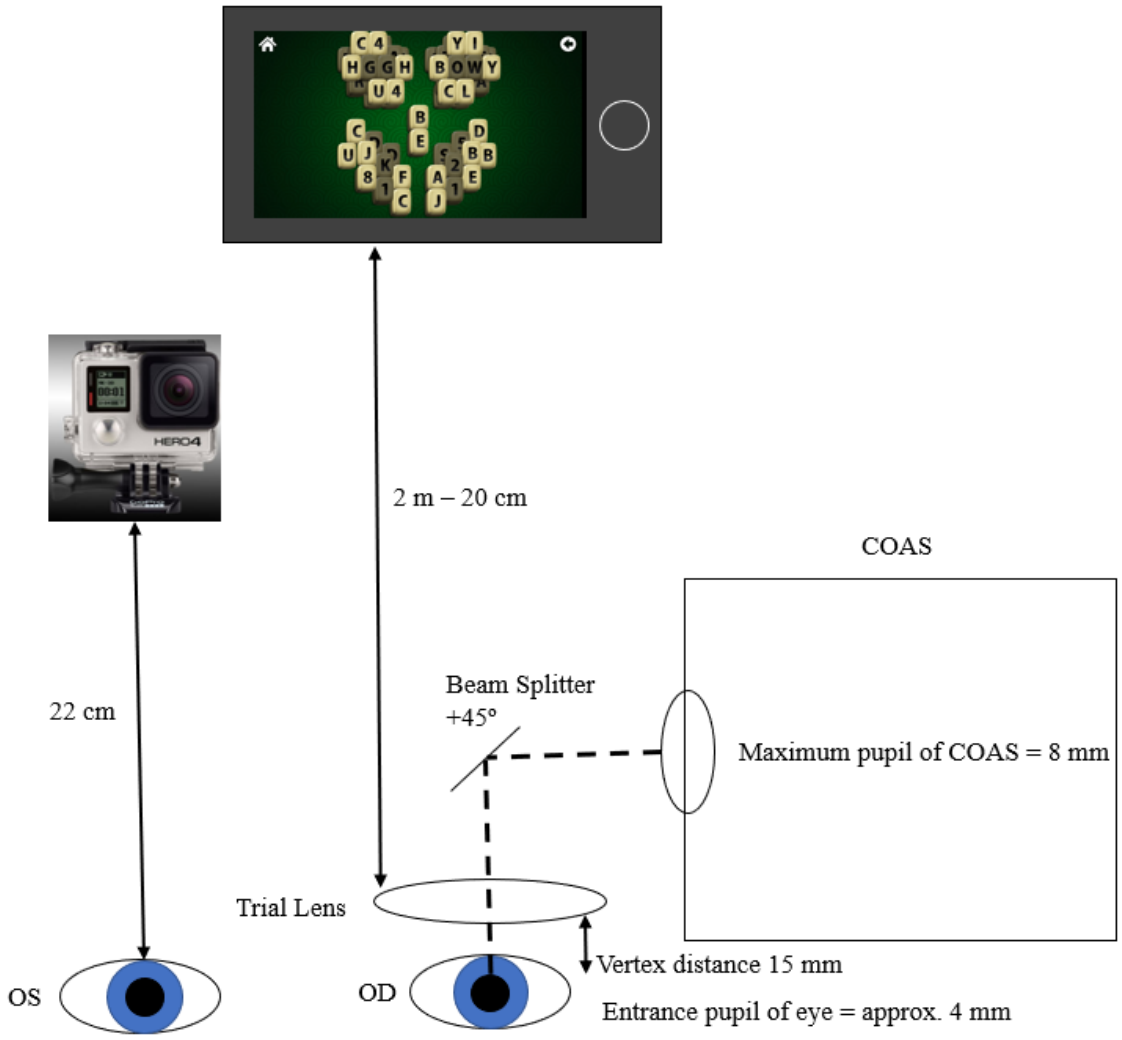
Testing stimulus: Mahjong Game Screen

- Asthenopia Induction testing equipment: +0.50 DS trial lens for distance testing (needed to optically create the 2 M stimulus item), eye patch for monocular testing scenarios, -3.00 DS lens flipper for binocular flipper condition, -3.00 DS trial lens for monocular flipper condition, +5.00 DS spectacles to eliminate accommodative demand for the close working distance (20 cm) condition, timer to track testing time up to maximum 15 minutes

  A schematic of the COAS and optics table organization may be seen in Figure 3.

Figure 3

Schematic of COAS and Optics Table Organization



To accurately quantify each participant's data, baseline testing was performed on each participant before the induction testing began. Binocular distance baseline testing was performed at the beginning and end of the study, to measure resting accommodation at optical infinity. A single maximum cycle of 43 image captures by the COAS at a frame rate of 2 seconds were captured under this condition. This translates to 1 minute 26 seconds in this testing configuration. To ensure the accurate display of a 20/20 Snellen letter stimulus item, the 2 M stimulus (Snellen

Letter E, see Figure 1) was placed at a distance of 200 cm from the COAS and a +0.50 DS lens was placed in the COAS lens well in front of the participant's right eye. (To subtend a 20/20 acuity letter size, a 1 M stimulus placed at 1 meter distance would be 1.45 mm in height viewed through a +1.00 DS lens; at 2 meters, or 200 cm, the 2 M stimulus would be 2.91 mm in height viewed through a +0.50 DS lens.) Additional baseline testing using the study stimulus item (Mahjong Solitaire Epic played on the iPhone screen controlled by the MacBook; for the operating procedures, see Appendix 3) was performed at the test distance of 40 cm from the COAS lens well (spectacle plane of eye), under binocular and monocular conditions. The stimulus was presented for the maximum time of 15 minutes, spliced into 10.46 cycles of 43 COAS image captures. This data could then be compared to each participant's induction test results, to determine if a change to the patient's accommodative state was created by the test scenario.

High quality image capture of the testing scenarios was performed by video recording with the GoPro Hero 4 silver edition camera. The camera was placed at 22 cm from the participant's pupil plane. To ensure accurate measurement during each test, image capture of a PD stick placed at the participant's pupil plane before each testing scenario provided information for the conversion of pixels to millimeters to be used in analysis. Analysis of the participant's blink rate could be performed by viewing the video recording and counting blinks. Standard operating procedures for the GoPro Hero 4 may be found in Appendix 4.

Non-invasive tear break up time was measured by the researcher using the Medmont E300 corneal topographer.[77] Instructions given to the participant was to blink three times, then hold eyes open wide until they were unable. The researcher watched the topographer's mires reflected off of the surface of the participant's contact lens or cornea, for the blurring, or disruption of mires to start. Time (seconds) to mire distortion was counted as tear break up time.[78] This process was repeated 3 times per eye, and results were averaged together to create a single value for analysis. These measures could then be analyzed within subjects and between subjects, to rule out dryness of the contact lens as a confounding factor in the testing scenarios.

At maximum, the participant was allowed 15 minutes to perform each task, but could stop the timer at any time once "barely tolerable eyestrain" was achieved.[79] Additionally, the participant was instructed to stop time if the iPhone screen could no longer be kept clear and single (e.g. if insurmountable diplopia or blur were to occur). If the participant concluded the 15 minutes, a survey question of "percentage of barely tolerable eyestrain" was asked (see Appendix 2). Time at which the participant stopped playing the Mahjong game was recorded, as well as the total number of puzzles completed and number of "stars" or game points achieved (up to a maximum of 3: completion of board, no hint or shuffle of tiles, and completion time under game expectation as programmed into the software) was recorded. To prevent memorization of any puzzle, participants never repeated the same puzzle. All puzzles presented were of same level of difficulty.

[77] Kojima R, Caroline P, Kinoshita B, Lampa M, André M, Rosen C. Applications of Corneal Topography Beyond Corneal Shape. Contact Lens Spectrum. November 1, 2013. Available at: http://www.clspectrum.com/issues/2013/november-2013/applications-of-corneal-topography-beyond-corneal. Accessed September 3, 2017.
[78] Situ P, Simpson TL, Fonn D, Jones LW. Conjunctival and Corneal Pneumatic Sensitivity is Associated with Signs and Symptoms of Ocular Dryness. Investigative Ophthalmology and Vision Science. 2008 Jul. 49(7): 2971-2976.
[79] Sheedy JE, et al. Is All Asthenopia the Same?

The EFRQ was presented before testing commenced (the participant was to answer the questions based overall or average daily symptoms), after all testing was completed (based on severity of symptoms after all study testing was complete), and immediately before and immediately after each testing scenario (based on severity of symptoms "right now"). The purpose was to have a subjective measure of the participant's symptoms of asthenopia to correlate with the objective measures gathered during the study.

The four testing conditions, binocular flippers, monocular flippers, close working distance, and small font, were selected for this study. The conditions were chosen based on successful asthenopia induction procedures presented in past literature, that could be performed in the COAS set up. The first two conditions, binocular and monocular flippers, placed the testing stimulus (iPhone) at a 40 cm working distance with a full-screen representation of the Mahjong game. In the binocular condition, participants were instructed to begin with the plus-powered lenses in front of their eyes, and in the monocular condition (with the left eye patched) instructed to perform the first matching set on the Mahjong game without the trial lens in place. A single match was to be performed with each flip of the lenses, in the binocular condition from no lens to -3.00 DS, and in the monocular condition from no lens to -3.00 DS. Before the match could be made, the participant was instructed to focus on the iPhone screen so that it appeared clear and single. If that was not achievable or if the patient reached a discomfort level of "barely tolerable eyestrain," the participant was instructed to stop time. The design of the third condition, close working distance, brought the testing stimulus (iPhone) to a 20 cm working distance. +5.00 DS spectacles were worn to eliminate the accommodative strain incurred at the test distance. The fourth, small font condition task set up returned the iPhone to a 40 cm working distance, but

shrank the size of the images on the Mahjong tiles to 1mm in height. This was achieved by shrinking the size of the Mahjong game on the MacBook Pro to 4.25 inches x 3 inches.

Lastly, post-test measures included a repeat of the baseline tests performed. In total, the average time required for the study procedure was 1.6 hours for the screening-visit and 3.75 hours for the study-visit. Two study visits were completed by a total of eight participants (total number of participants required to eliminate any order effect within the four asthenopia induction testing categories, based on a balanced repeated Latin square randomization design, see Table 3).[80]

[80] Dubcovsky, J. Double Block Designs: Latin Squares. Archive of Experimental Design Course PLS205 (Winter 2015). Department of Plant Sciences, University of California – Davis. Available at: http://www.plantsciences.ucdavis.edu/agr205/lectures/2011_lectures/l7_latinsq.pdf. Accessed September 10, 2017.

Table 3

Randomization

Key	Initial randomization	Latin Square Order
1	Close Working Distance	1 2 4 3
2	Binocular Flippers	2 3 1 4
3	Monocular Flippers	3 4 2 1
4	Small Font	4 1 3 2

Subject	Induction 1	Induction 2	Induction 3	Induction 4
1	Close Working Distance	Binocular Flippers	Small Font	Monocular Flippers
2	Binocular Flippers	Monocular Flippers	Close Working Distance	Small Font
3	Monocular Flippers	Small Font	Binocular Flippers	Close Working Distance
4	Small Font	Close Working Distance	Binocular Flippers	Monocular Flippers
5	Close Working Distance	Binocular Flippers	Small Font	Monocular Flippers
6	Binocular Flippers	Monocular Flippers	Close Working Distance	Small Font
7	Monocular Flippers	Small Font	Binocular Flippers	Close Working Distance
8	Small Font	Close Working Distance	Binocular Flippers	Monocular Flippers

COAS aberrometer data was exported and interpreted via established MatLab and Microsoft Excel code.[81,82]

Statistical analysis was performed via the linear model for the Latin square:[83]

$$y_{ij(t)} = \mu + \beta_i + \gamma_j + \tau_{(t)} + \varepsilon_{ij}$$

Where:

$y_{ij(t)}$ represents the outcome variables for each participant

μ represents the baseline mean for all participants

β_i represents effect of the i^{th} subject order (based on row blocking)

γ_j represents the effect of the j^{th} subject order (based on column blocking)

τ_t represents the treatment effect

ε_{ij} represents random error from the i^{th} row and j^{th} column

The test hypothesis was a comparison of H_o: $\tau_t = 0$ versus H_i: $\tau_t \neq 0$. The p-value was set to 0.05.

The ANOVA table for a repeated Latin square analysis may be seen in Table 4:[84]

[81] Liu, T. Extract Zernike Coeff. Custom MatLab Code. July 2012.
[82] Altoaimi, B. Template for Interpreting Pupil Size, Defocus, and up to 8th order Zernike Coefficient COAS Data Output. Custom Microsoft Excel Code. November 2015.
[83] Dubcovsky, J. Double Block Designs: Latin Squares.
[84] Ibid.

Table 4

ANOVA Table for Repeated Latin Square

Source	**Df**	**SS**	**MS**	**F**
Rows	r – 1	SSR	SSR/(r-1)	MSR/MSE
Columns	r – 1	SSC	SSC/(r-1)	MSC/MSE
Treatments	r – 1	SST	SST/(r-1)	MST/MSE
Error	2(r-1)(r-2)	SSE	SSE/(2(r-1)(r-2))	
Total	r^2-1	TSS		

Where:

df represents degrees of freedom

SS represents sum of squares

MS represents mean squares

F represents the F-statistic

r represents rows (in this experimental design, r = 4, as 4 rows are accounted for; see Table 2.)

SSR represents sum of squares between rows

SSC represents sum of squares between columns

SST represents sum of squares between treatments

SSE represents error sum of squares

TSS represents total sum of squares

MSR represents mean square between rows

MSC represents mean square between columns

MST represents mean square between treatments

MSE represents mean square error

Results

Four categories of results were extrapolated from the data collected. (1) Non-invasive tear break up time; (2) Symptom severity scale; (3) COAS Aberrometer data (including refractive state, spherical aberration and pupil size); (4) Go-Pro camera video recording data (including time to fatigue and fissure height). The following tables and graphs represent the results in each category, which will be further analyzed in the discussion chapter.

Non-invasive tear break up time

Table 5.1

Change in Non-invasive tear break up time for each condition across subjects (post-test measure minus pre-test measure); for induction technique in order of performance, regardless of type

Participant	Induction Technique 1 (seconds)	Induction Technique 2 (seconds)	Induction Technique 3 (seconds)	Induction Technique 4 (seconds)
01	3.6	-0.3	0.3	0.6
03	4.3	-2	4.4	-2.7
05	-3	-2	0.3	-2.3
06	-6.3	0.6	2.4	-0.3
07	4.4	1.3	1	1
08	0.7	0.3	1.7	0.4
09	0.6	3.7	-4.3	-0.7
10	-1.7	0	0.7	-1.7
AVERAGE	0.325	0.2	0.8125	-0.7125

The negative values here indicate that the post-test tear break up time measurement was longer in duration than its corresponding pre-test measure. Positive values are the opposite: the post-test tear break up time measurement was shorter in duration than its corresponding pre-test measure.

Table 5.2

ANOVA results

	Induction Technique 1	Induction Technique 2	Induction Technique 3	Induction Technique 4	Total
N	8	8	8	8	32
∑X	2.6	1.6	6.5	-5.7	5
Mean	0.325	0.2	0.8125	-0.7125	0.1563
$\sum X^2$	103.24	23.92	48.17	17.57	192.9
Std Dev	3.8246	0.81361	2.4753	1.3892	2.4895

Source	SS	df	MS
Between	9.7263	3	3.2421
Within	182.3925	28	6.514
Total	192.1188	31	

F=0.49771
p=0.686857
Not Significant @ p<0.05

Table 6.1

Change in Non-invasive tear break up time for each condition across subjects (post-test measure minus pre-test measure); induction technique separated by type, regardless of order performed

Participant	Monocular Flippers (seconds)	Binocular Flippers (seconds)	Close Working Distance (seconds)	Small Font (seconds)
01	0.6	-0.3	3.6	0.3
03	-2.7	-2	-4.3	4.4
05	-2.3	0.3	-2	-3
06	0.6	-6.3	2.4	-0.3
07	1	1	1.3	4.4
08	0.7	1.7	0.4	0.3
09	3.7	0.6	-4.3	-0.7
10	1	0.7	-1.7	0
AVERAGE	0.325	-0.5375	-0.575	0.675

Table 6.2

ANOVA results

	Monocular Flippers	Binocular Flippers	Close Working Distance	Small Font	Total
N	8	8	8	8	32
∑X	2.6	-4.3	-4.6	5.4	-0.9
Mean	0.325	-0.5375	-0.575	0.675	-0.0281
$\sum X^2$	29.48	48.61	64.44	48.48	191.01
Std Dev	2.0226	2.5718	2.9712	2.5308	2.4821

Source	SS	df	MS
Between	9.4209	3	3.1403
Within	181.5638	28	6.4844
Total	190.9847	31	

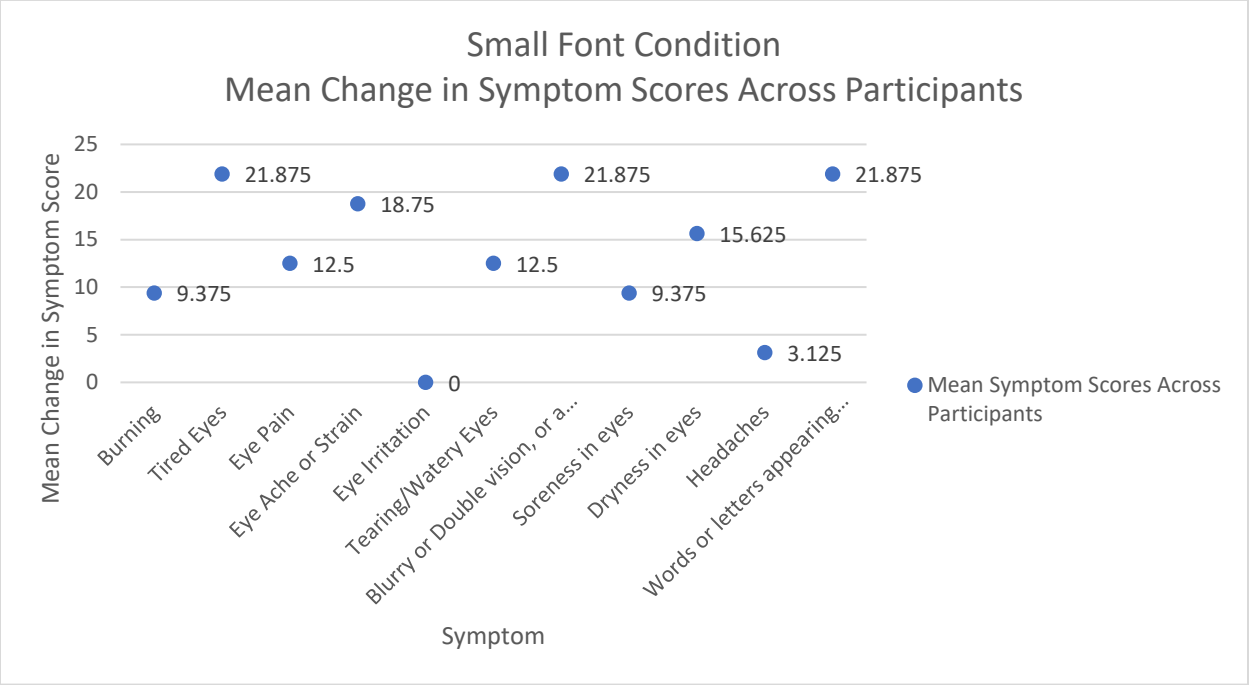
F=0.48429
p=0.695898
Not Significant @ p<0.05

The result of $p<0.05$ in both instances (tables 5.2 and 6.2) indicate no correlation between signs and symptoms of dry eye seen throughout any of testing conditions, regardless of test order or type.

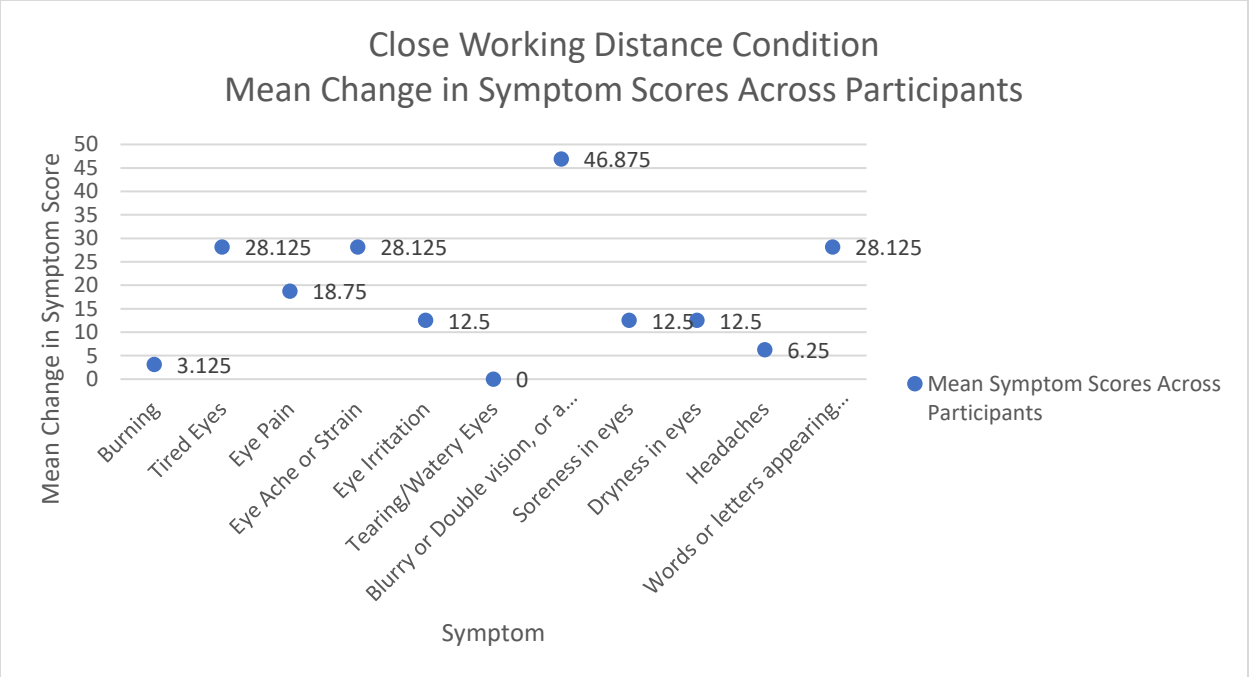
Symptom Severity Scale

The following eight graphs represent the mean change in symptom scores across participants for the symptom severity scale survey data collected. This was determined by calculating the change in each symptom score (post-test symptom score minus pre-test symptom score) for each participant and condition type, and calculating the average across participants for that condition and symptom. Graphs 1.1 through 1.4 represent the severity scale data analyzed by induction type, regardless of condition order performed. Graphs 1.5 through 1.8 represent the severity scale data analyzed by induction testing order, regardless of testing type.

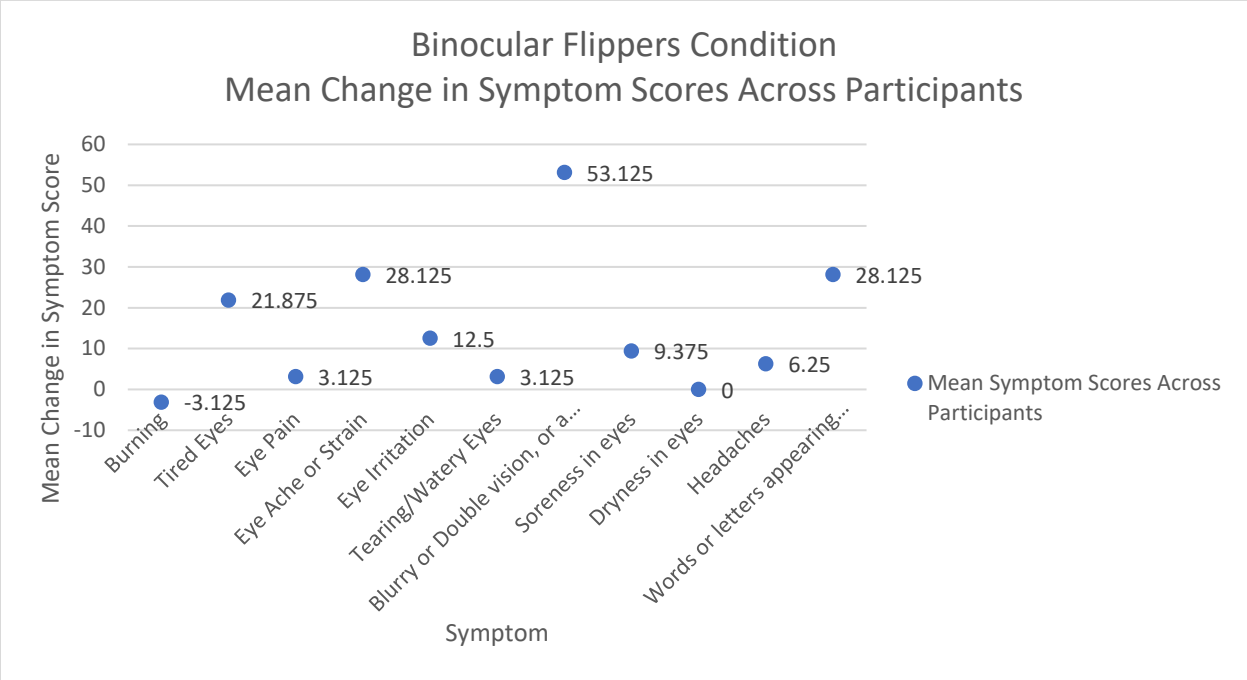
Graph 1.1



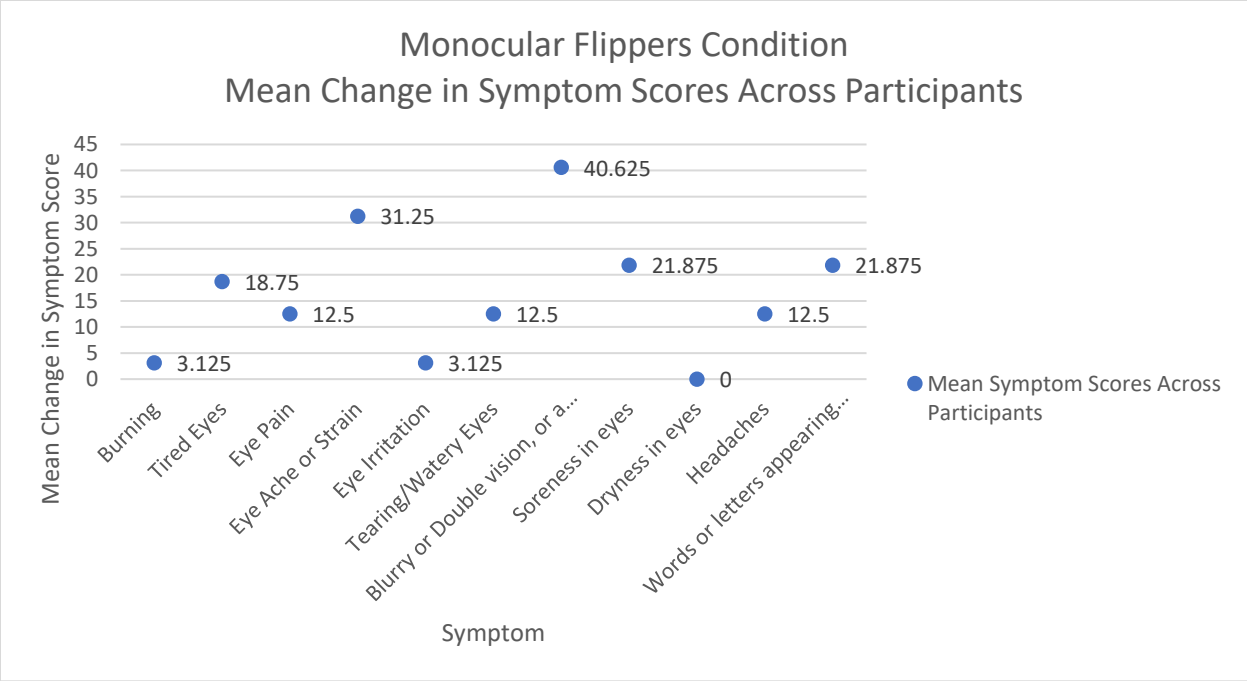
Graph 1.2



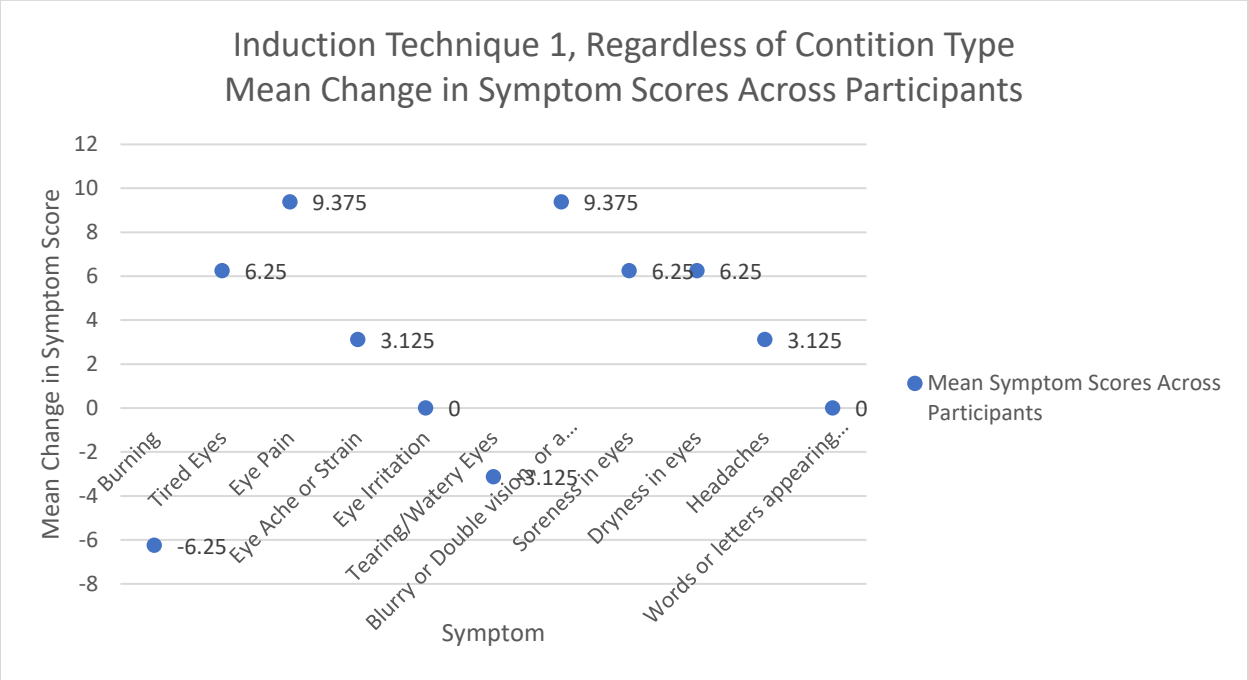
Graph 1.3



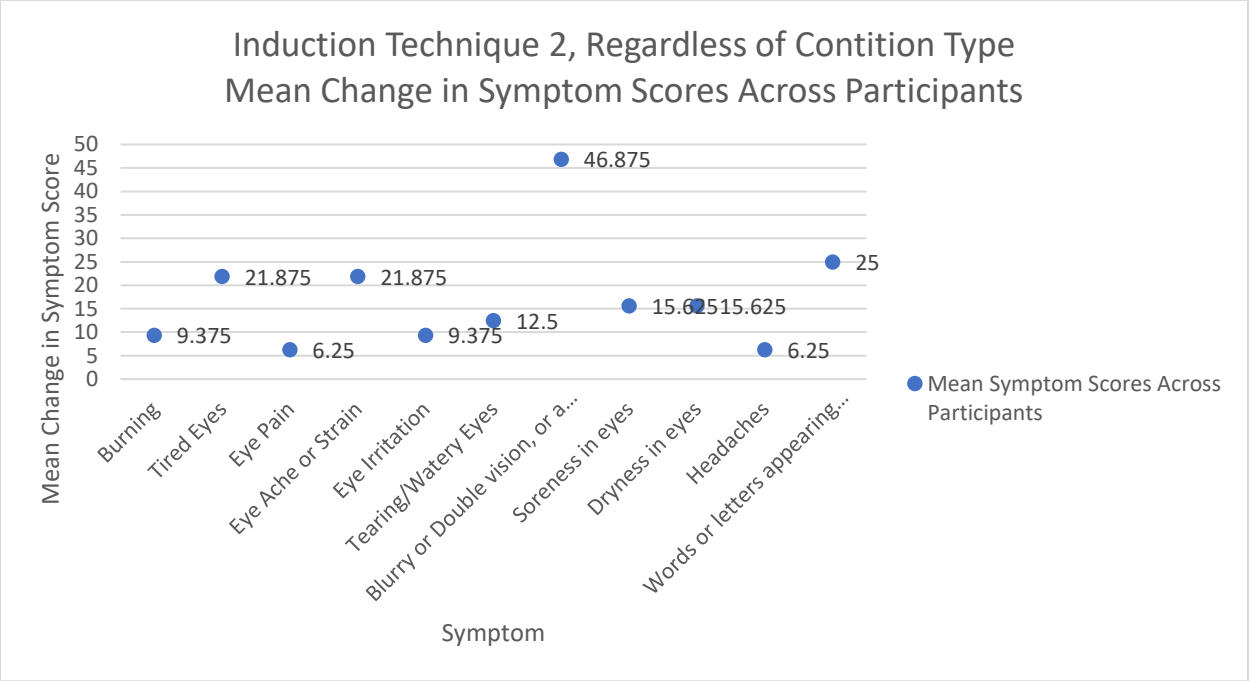
Graph 1.4



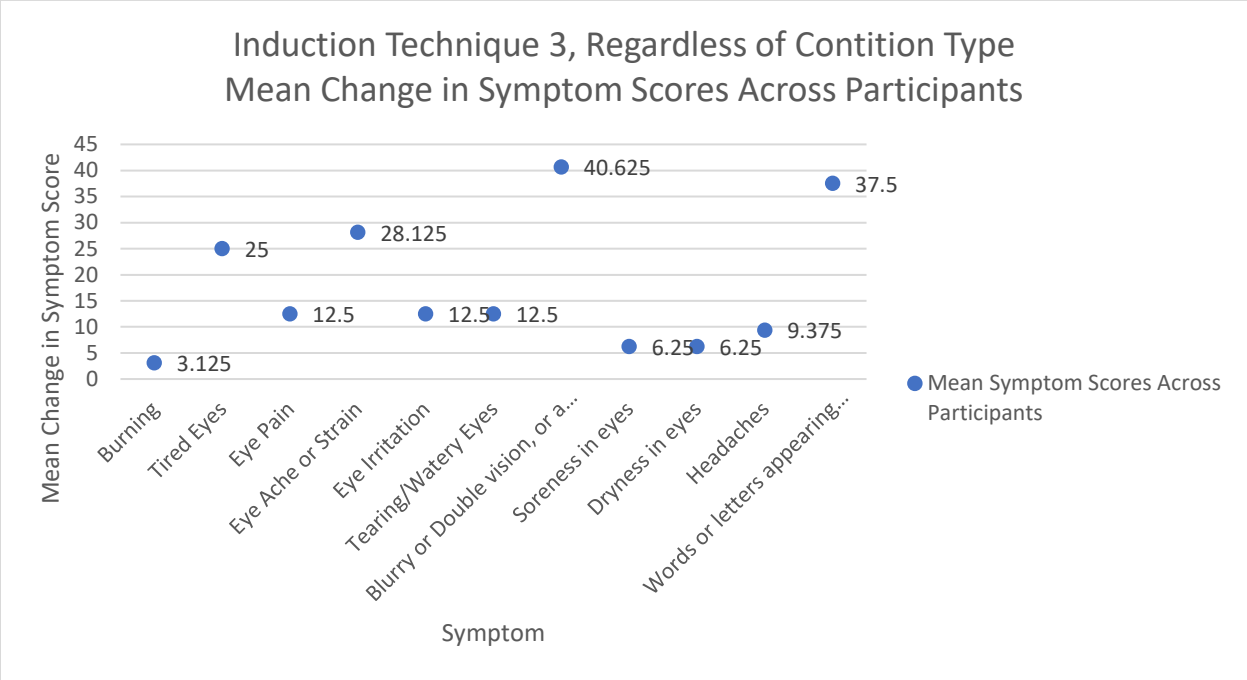
Graph 1.5



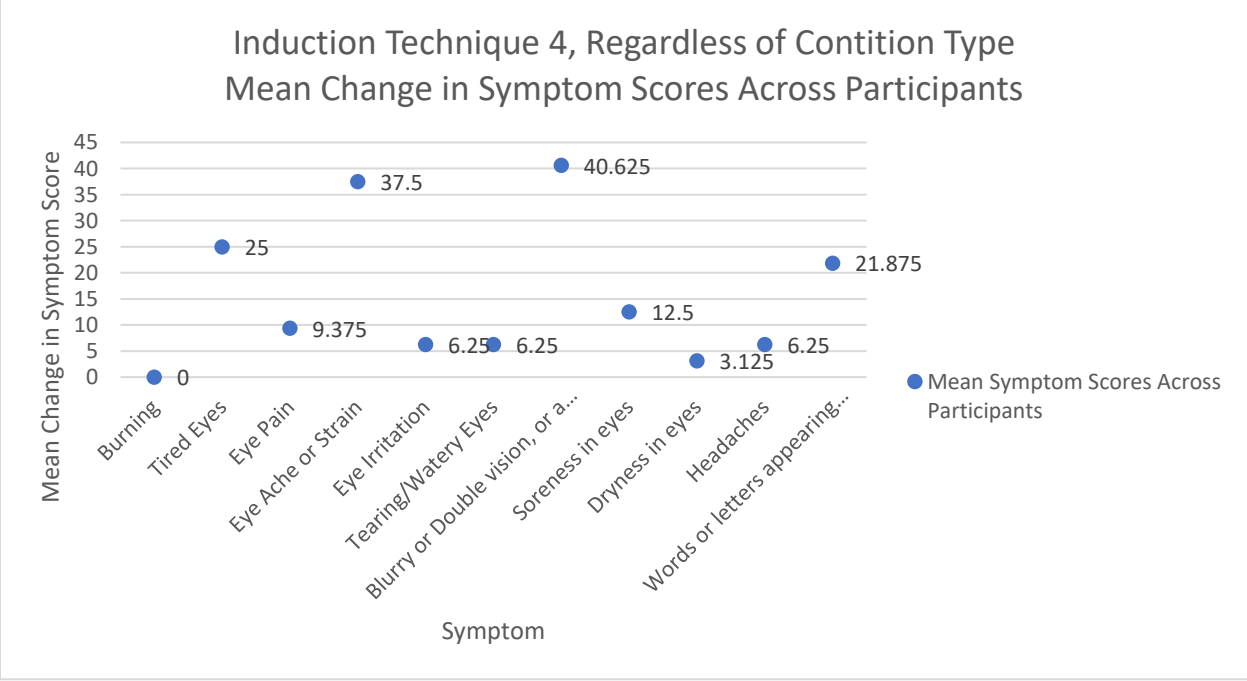
Graph 1.6



Graph 1.7



Graph 1.8



A two-tailed paired T-Test to determine if any difference in pre- and post-test severity scale scores were due to chance was performed for each participant in each condition. These results may be seen in Table 7.

Table 7

Two-tailed paired T-Test for two dependent means; Ho (that any difference in pre-and post-test severity scale scores are due to chance) is rejected if p<0.0125

(Bonferroni correction was utilized to determine the p-value: alpha of 0.05 divided by 4 induction testing categories equals new p-value of 0.0125. The Blue data in the following graph represents non-significance at p>0.0125; Red represents significance at p<0.0125.)

Participant	Induction Technique 1	Induction Technique 2	Induction Technique 3	Induction Technique 4	Monocular Flippers	Binocular Flippers	Close Working Distance	Small Font
01	0.02362735	0.22123505	0.05194242	0.03792897	0.03792897	0.22123505	0.02362735	0.05194242
03	0.43157875	0.05194242	0.79611286	0.05194242	0.05194242	0.05194242	0.43157875	0.79611286
05	insufficent data	0.01619707	0.01114965	0.01114965	0.01114965	0.01114965	0.01619707	insufficent data
06	0.22123505	0.00160697	0.00031508	0.02609689	0.00160697	0.22123505	0.00031508	0.02609689
07	0.00114311	0.0003766	0.0095826	0.00155332	0.00155332	0.0095826	0.0003766	0.00114311
08	0.01619707	0.1668896	0.13989121	0.13989121	0.01619707	0.13989121	0.13989121	0.1668896
09	0.04554128	0.0251115	0.02415812	0.05194242	0.0251115	0.04554128	0.02415812	0.05194242
10	0.11127906	3.6426E-05	0.0815534	0.23747165	0.11127906	0.0815534	0.23747165	3.6426E-05

ANOVA results of change in severity scale scores across participants (Table 8) are found below.

Table 8

ANOVA test results; Ho (that any difference in pre-and post-test severity scale scores are due to chance) is rejected if p<0.0125

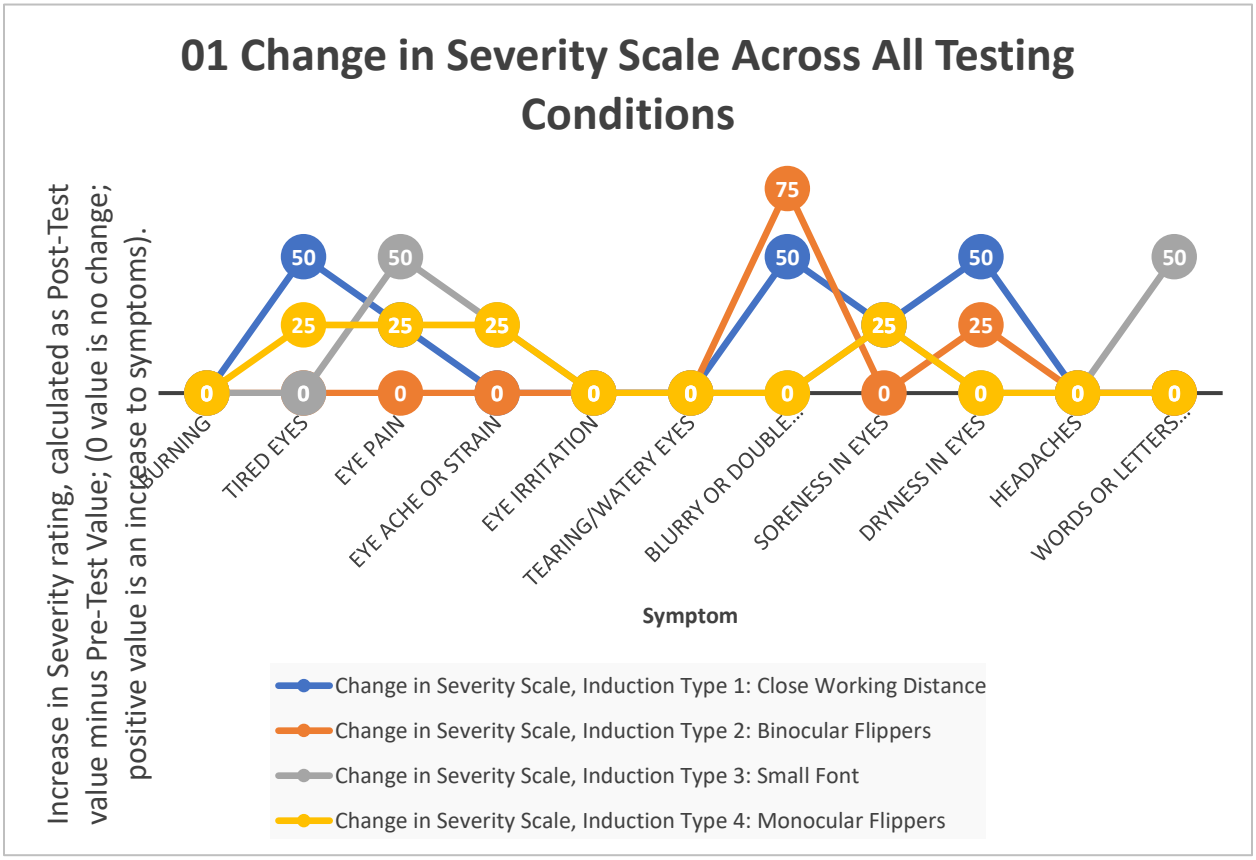
(Blue represents non-significance at p>0.0125; Red represents significance at p<0.0125. In this case, the Bonferroni corrected p-value and the standard alpha of 0.05 have the same number of significant outcomes.)

Small Font	P = 0.388
Close Working Distance	P = 0.003
Binocular Flippers	P = 0.000
Monocular Flippers	P = 0.000
Induction Technique 1	P = 0.968
Induction Technique 2	P = 0.000
Induction Technique 3	P = 0.009
Induction Technique 4	P = 0.000

As may be seen by the large number of significant results, much of the mean change in severity scale symptom scores are not due to chance. This was further explored by comparing the change in severity scale (post-test results minus pre-test results) for each participant in each condition. The following graphs (organized by participant) highlight what is occurring throughout the testing scenarios, with colored dots representing the change in severity scale results during the testing conditions. A value of zero indicates no change in score, positive values indicate a worsening of symptoms, and negative values indicate an improvement to symptoms.

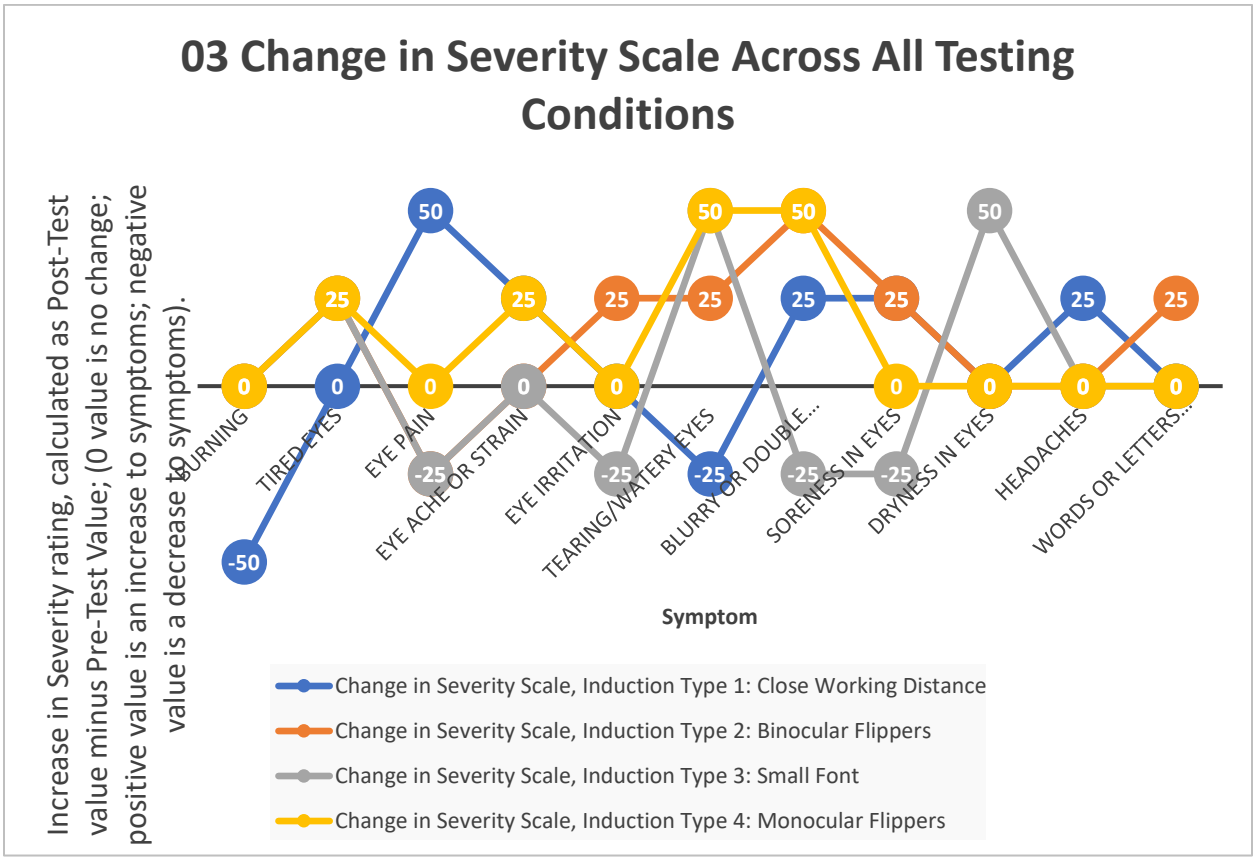
Graph 2.1

Participant 01 Change in Severity Scale Graph



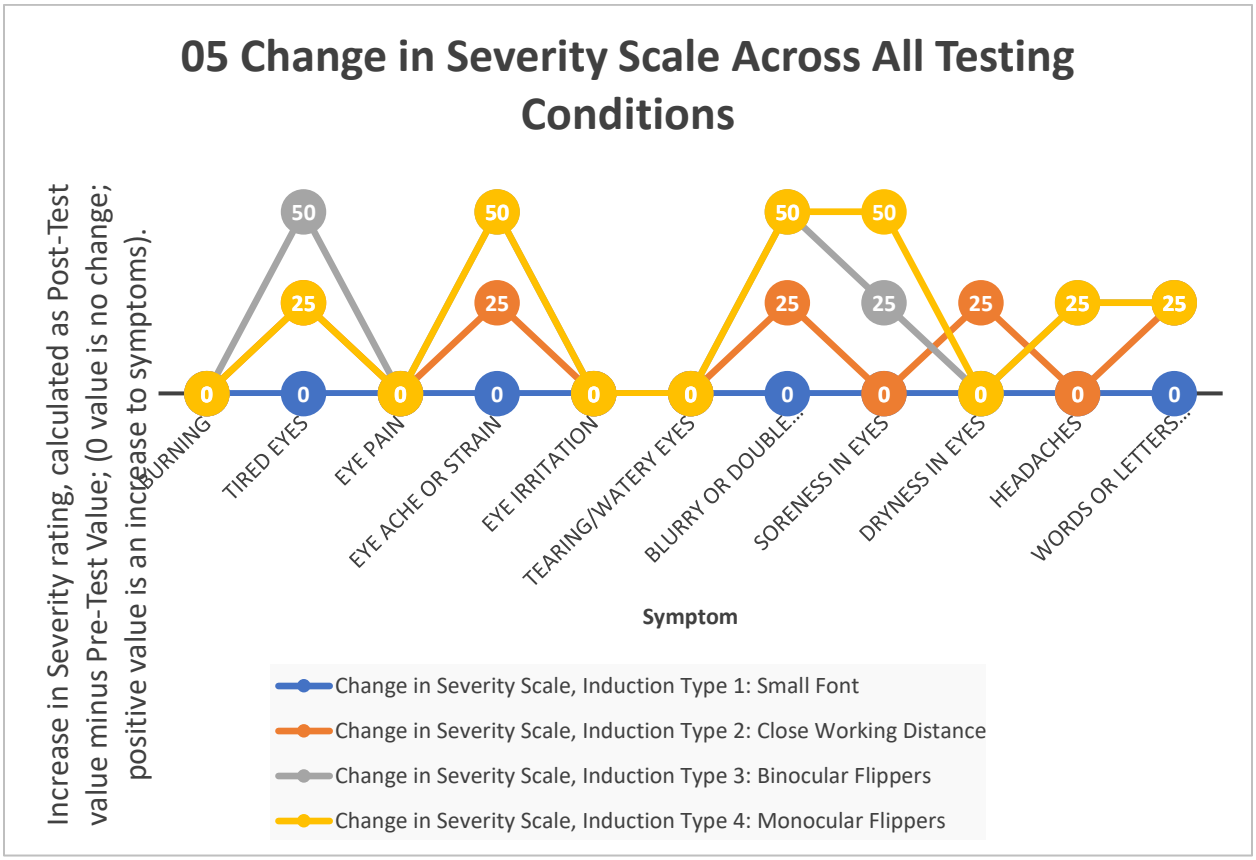
Graph 2.2

Participant 03 Change in Severity Scale Graphs



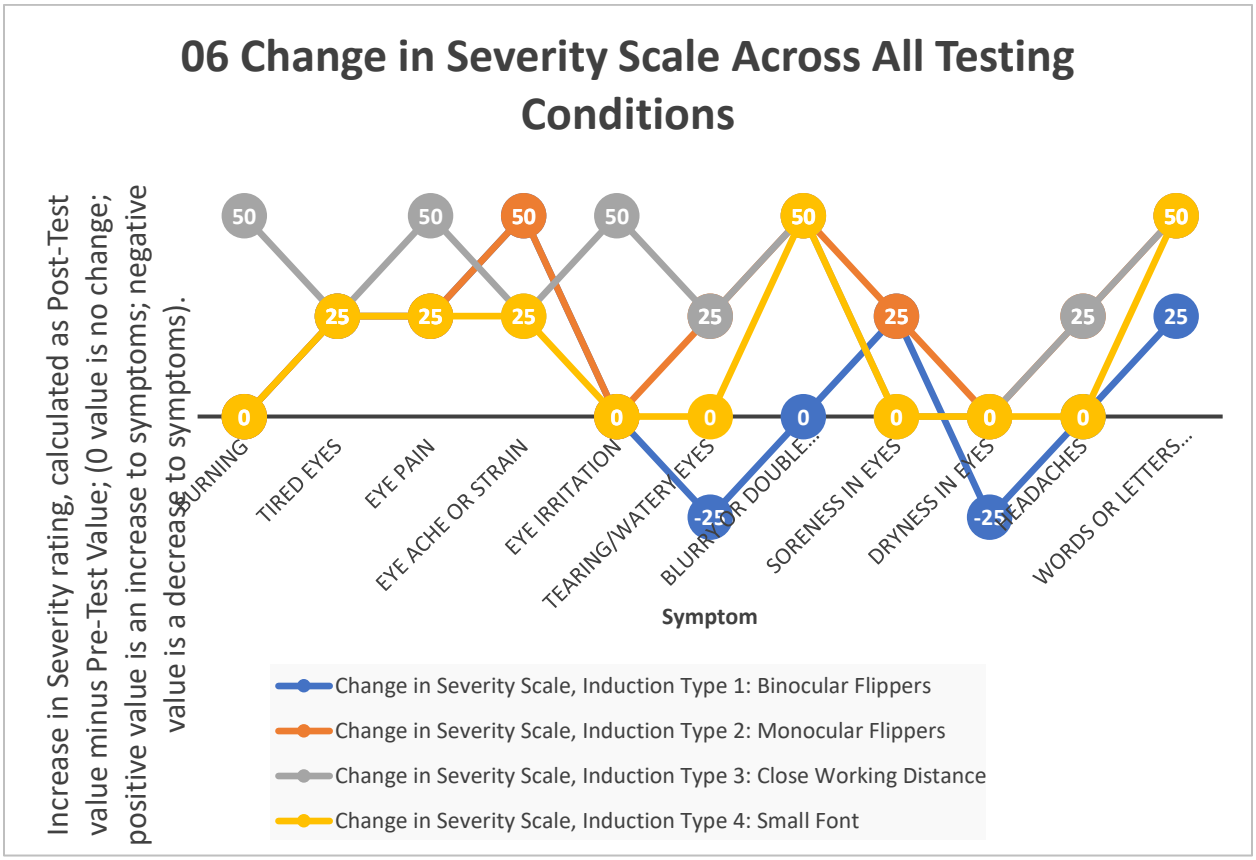
Graph 2.3

Participant 05 Change in Severity Scale Graphs



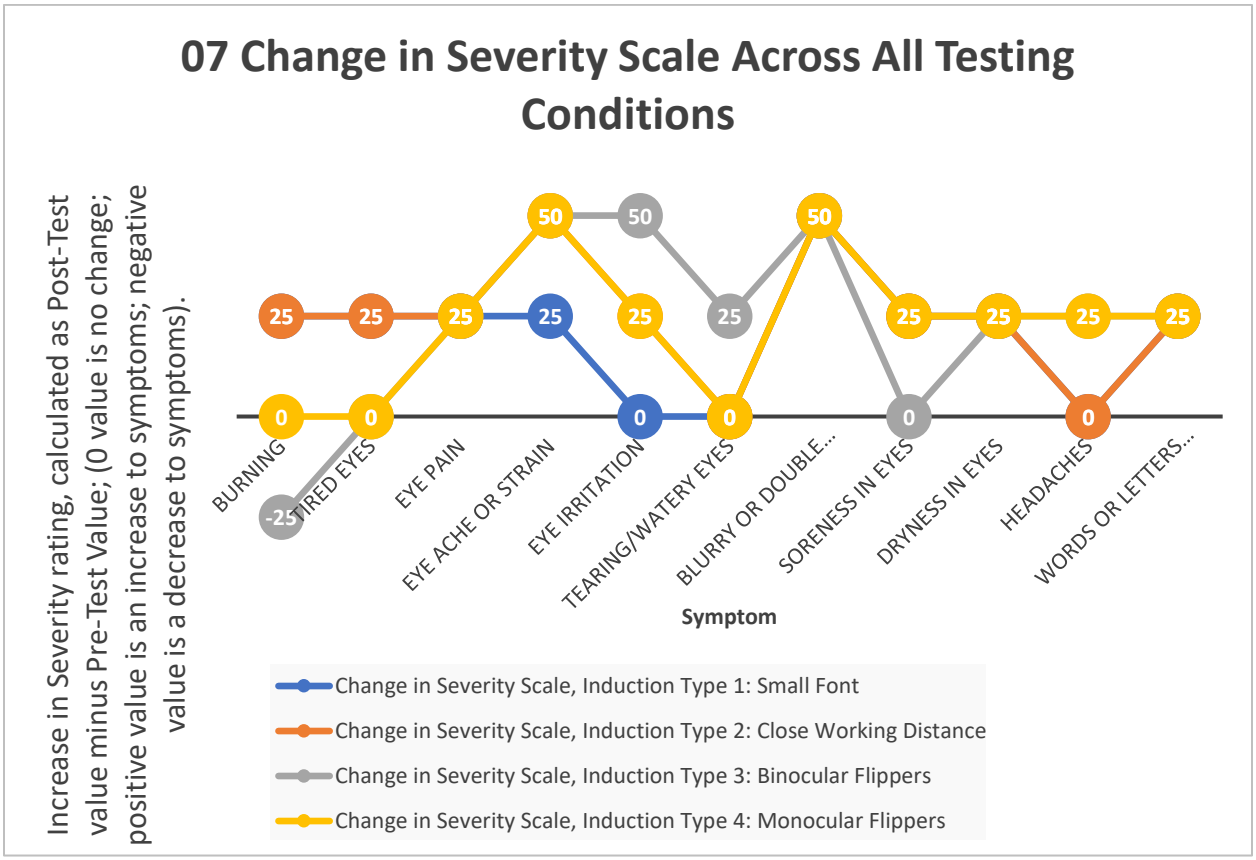
Graph 2.4

Participant 06 Change in Severity Scale Graphs



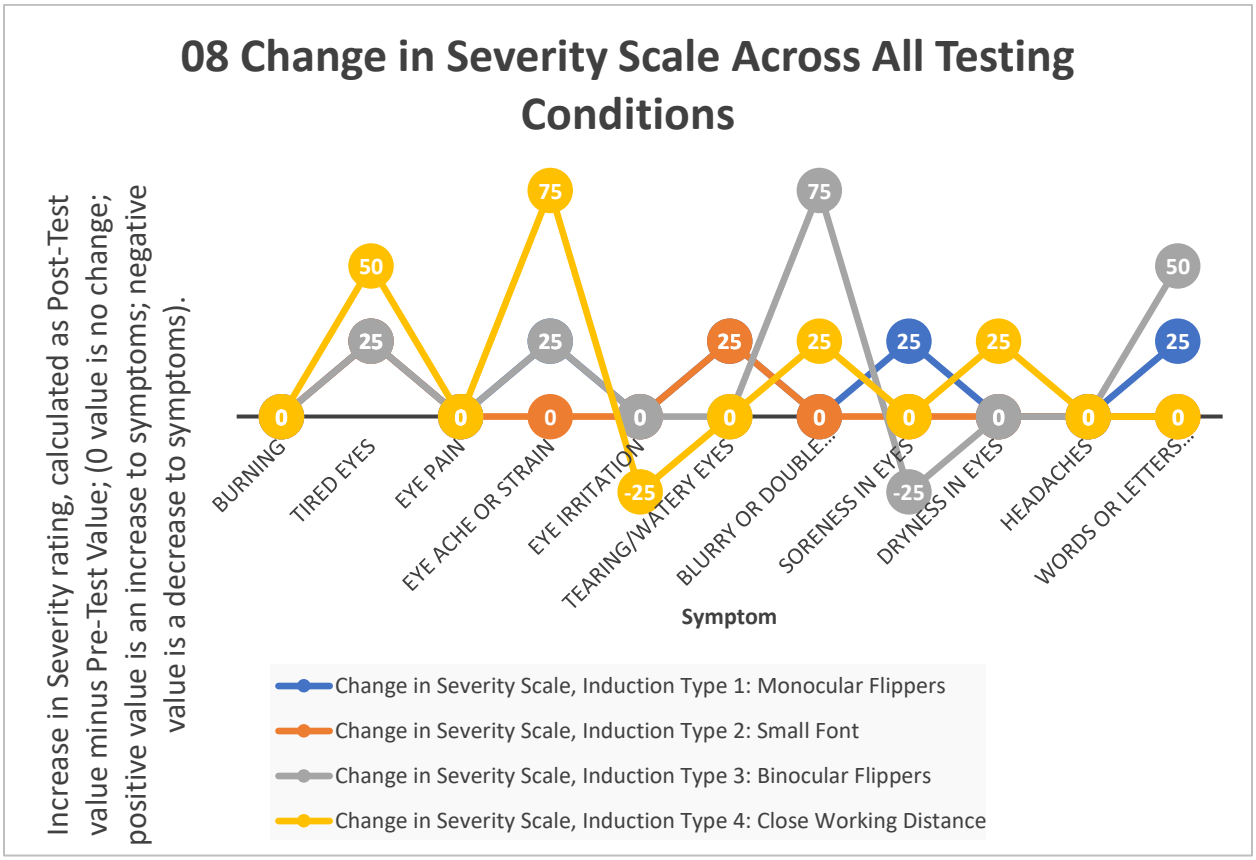
Graph 2.5

Participant 07 Change in Severity Scale Graphs



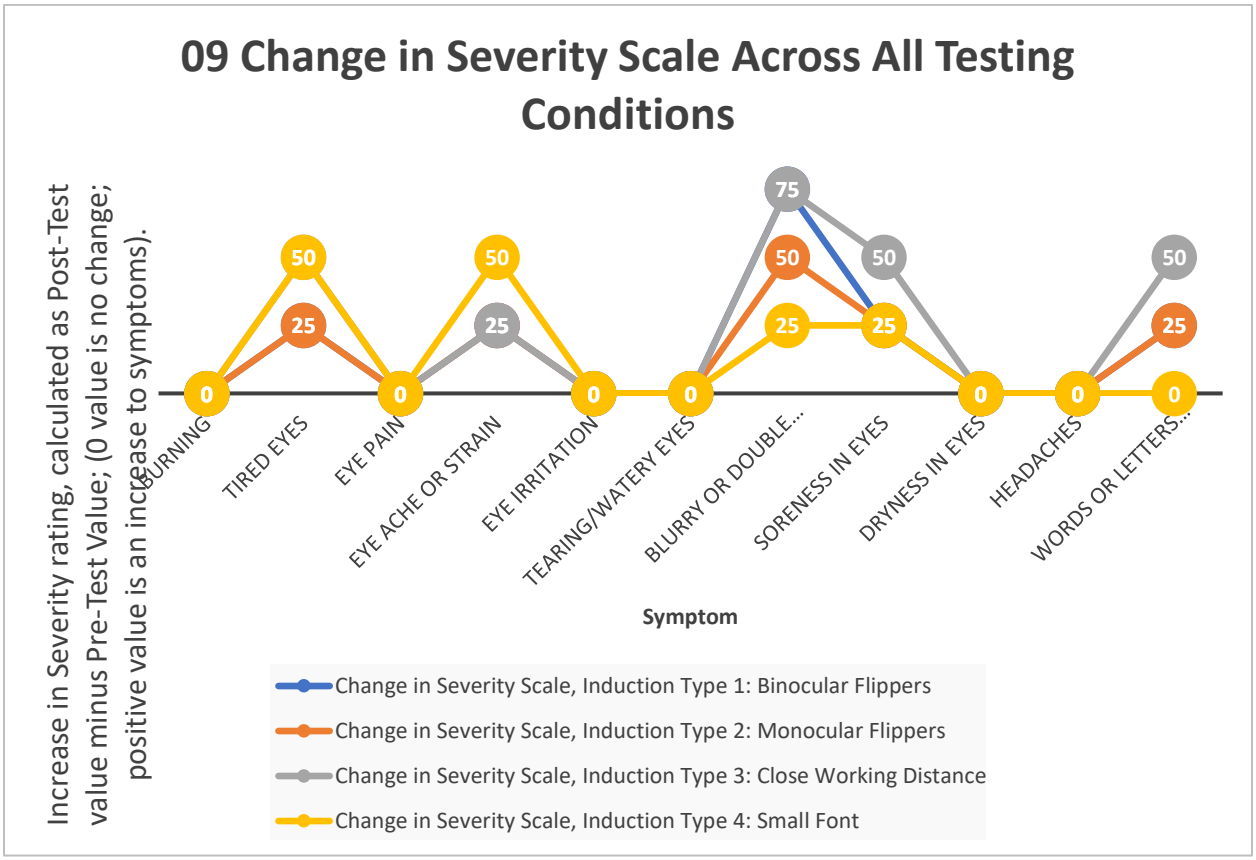
Graph 2.6

Participant 08 Change in Severity Scale Graphs



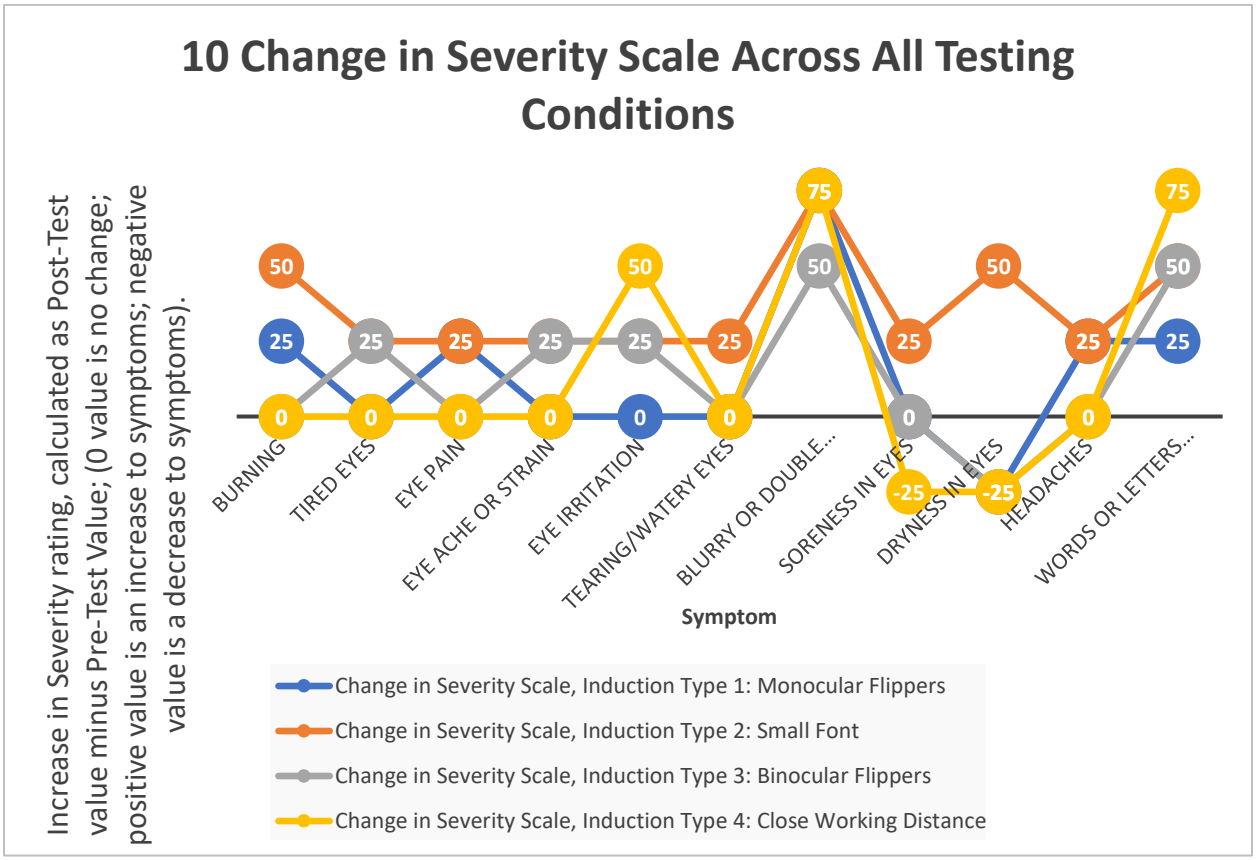
Graph 2.7

Participant 09 Change in Severity Scale Graphs



Graph 2.8

Participant 10 Change in Severity Scale Graphs



COAS Aberrometer Data

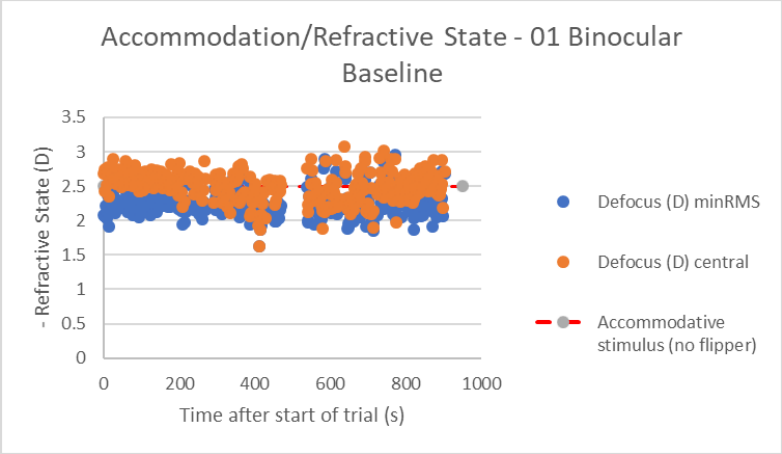
Refractive state data, spherical aberration and pupil size as captured by the COAS Aberrometer was compiled for each participant in each task condition (close working distance, binocular flippers, monocular flippers and small font). Binocular and monocular baseline data provided a control for all three subsets of COAS data. The following graphs represent each induction technique plus baseline testing compiled onto individual graphs, separated by participant.

Graphs 3.1a-f through 3.8a-f present refractive state versus time. Due to the complex nature of this data (defocus data analyzed both as minRMS and central for each condition and the varying amounts of expected accommodative stimulus based on condition) these graphs are presented below in sets of 6 for each participant (one graph each for binocular baseline, monocular baseline, close working distance, binocular flippers, monocular flippers and small font).

This data is then further parsed into analysis of the central refractive data only, as pupil size is not a factor in those measurements. Refractive state error is presented in graphs 4.1 through 4.8, graphs 5.1 through 5.6, and table 9. The variance in the refractive state error is presented in graphs 6.1, 6.2 and tables 10 and 11.

Graph 3.1a

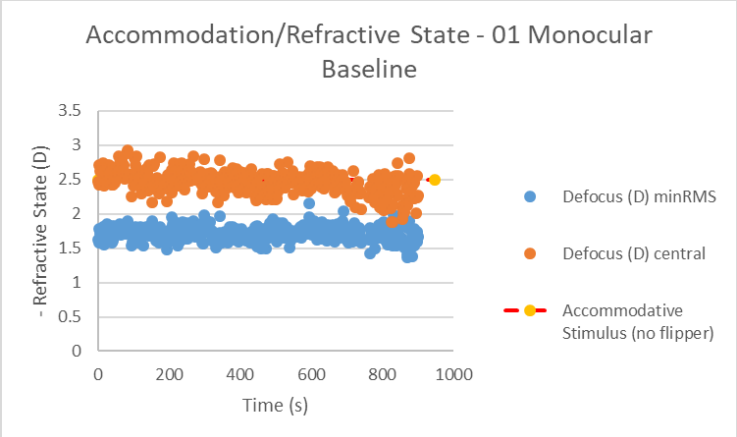
Participant 01 Binocular Baseline Refractive State versus Time



Gaps in the data, such as that found at 500 seconds, were missing due to a combination of involuntary data corruption (e.g. when COAS image capture did not provide usable data for analysis) and/or voluntary data corruption (e.g. when participants did not follow the instructions given by the investigator.) These can be found across conditions and in data from all participants, and is explored in depth in the discussion section.

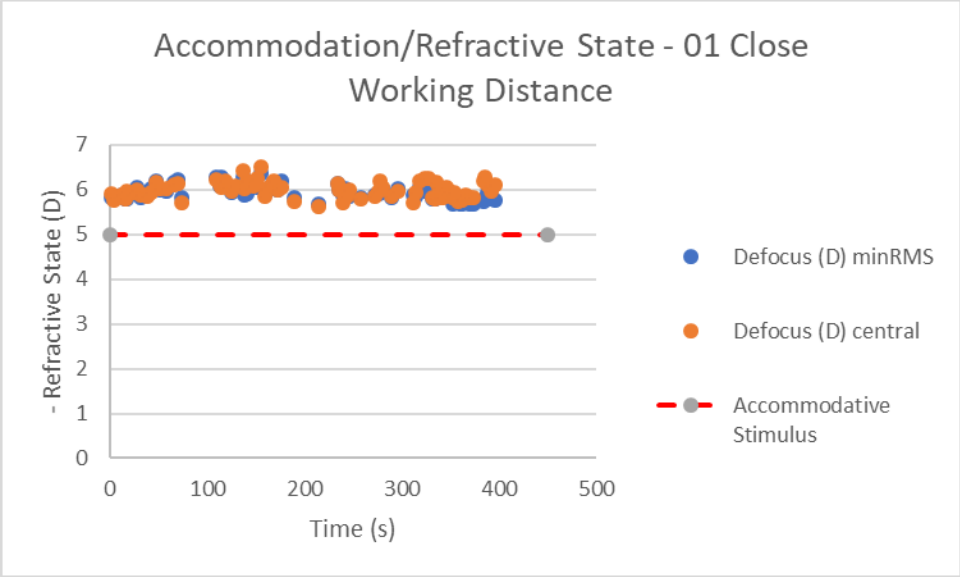
Graph 3.1b

Participant 01 Monocular Baseline Refractive State versus Time



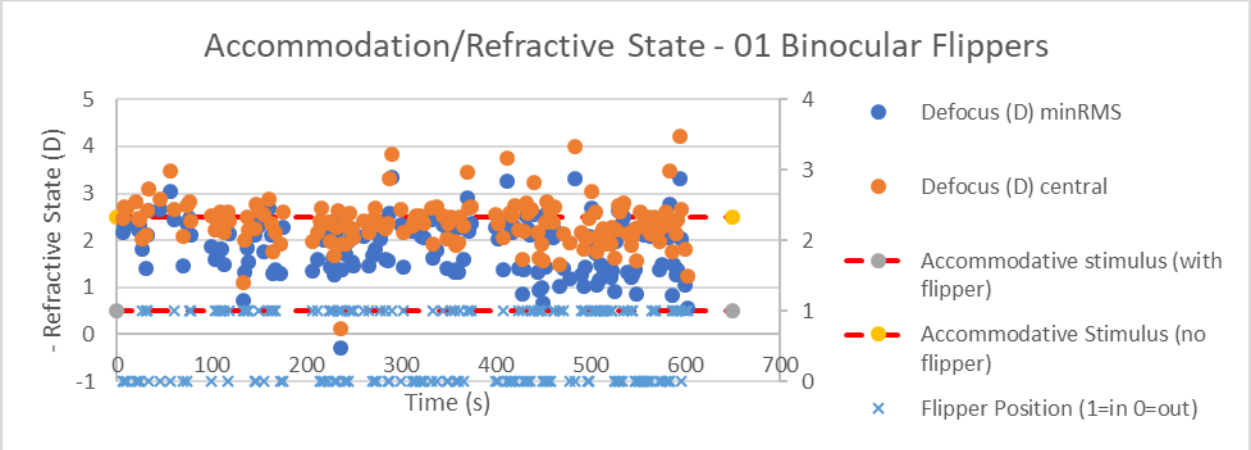
Graph 3.1c

Participant 01 Close Working Distance Refractive State versus Time



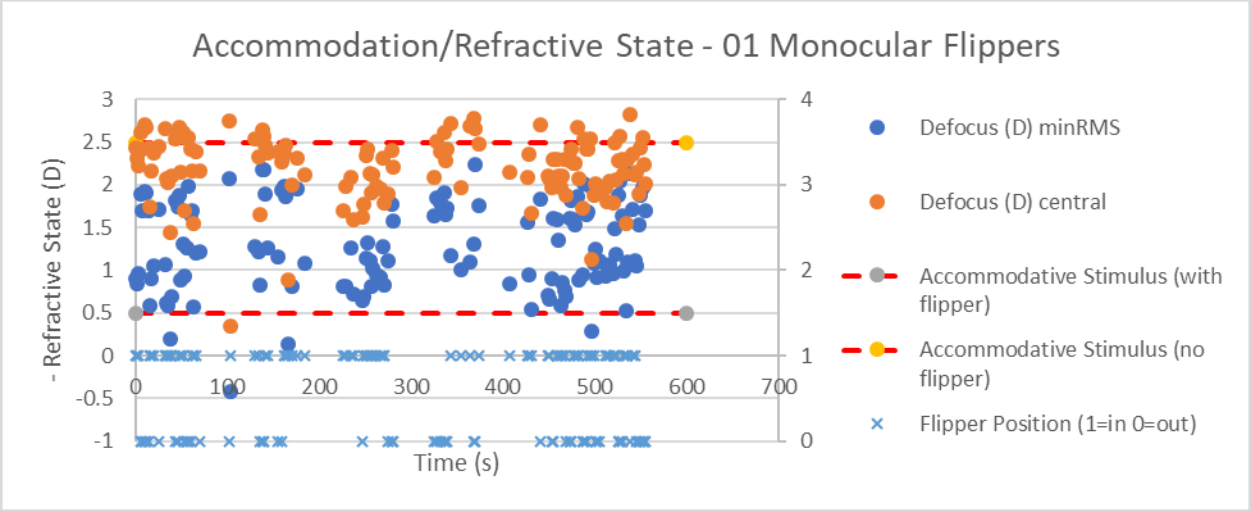
Graph 3.1d

Participant 01 Binocular Flippers Refractive State versus Time



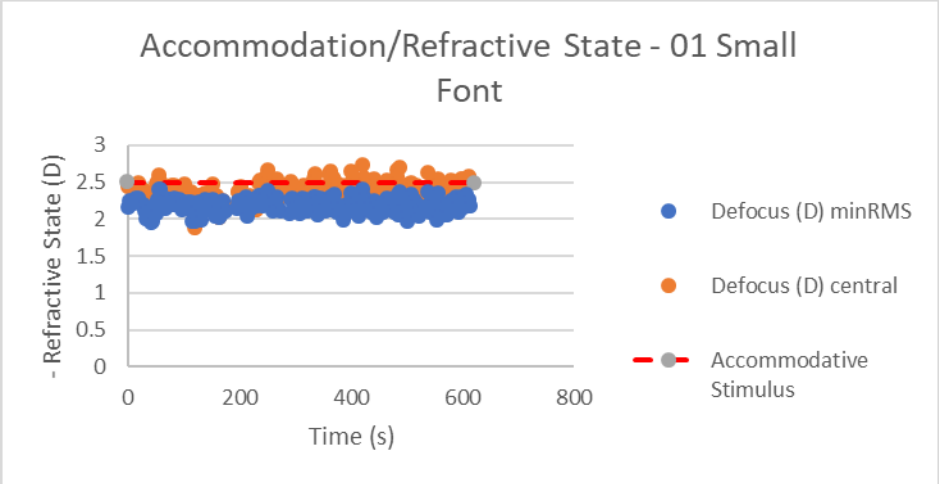
Graph 3.1e

Participant 01 Monocular Flippers Refractive State versus Time



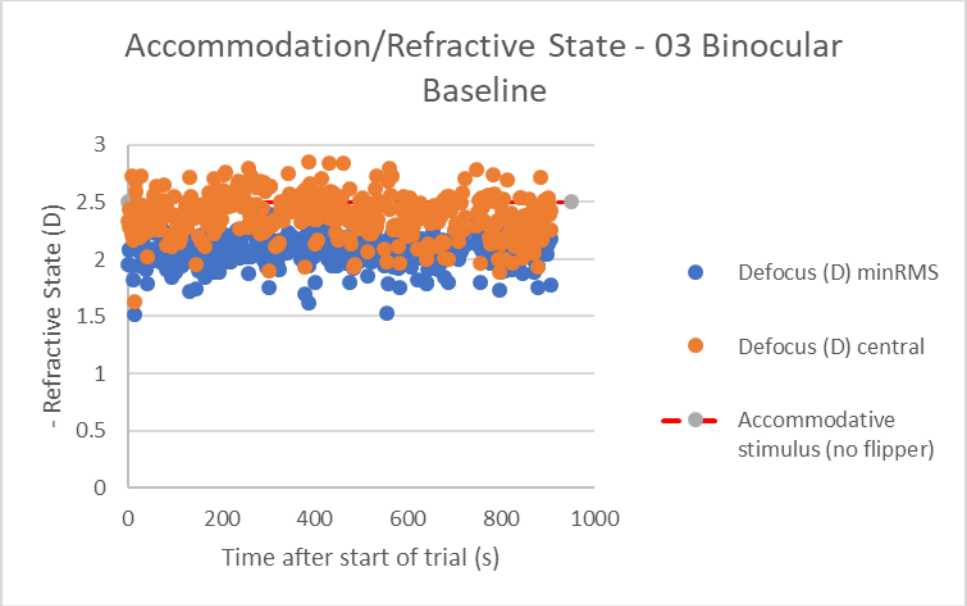
Graph 3.1f

Participant 01 Small Font Refractive State versus Time



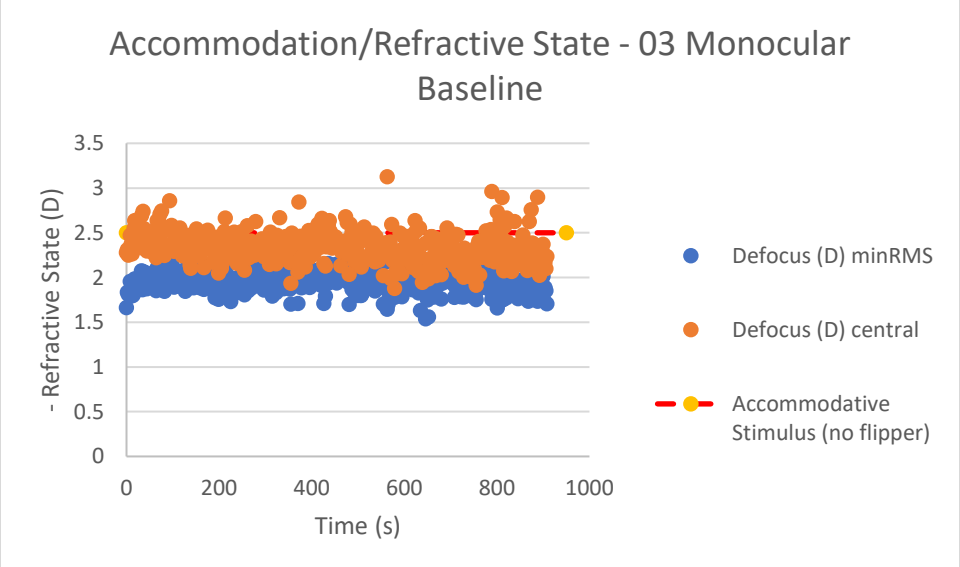
Graph 3.2a

Participant 03 Binocular Baseline Refractive State versus Time



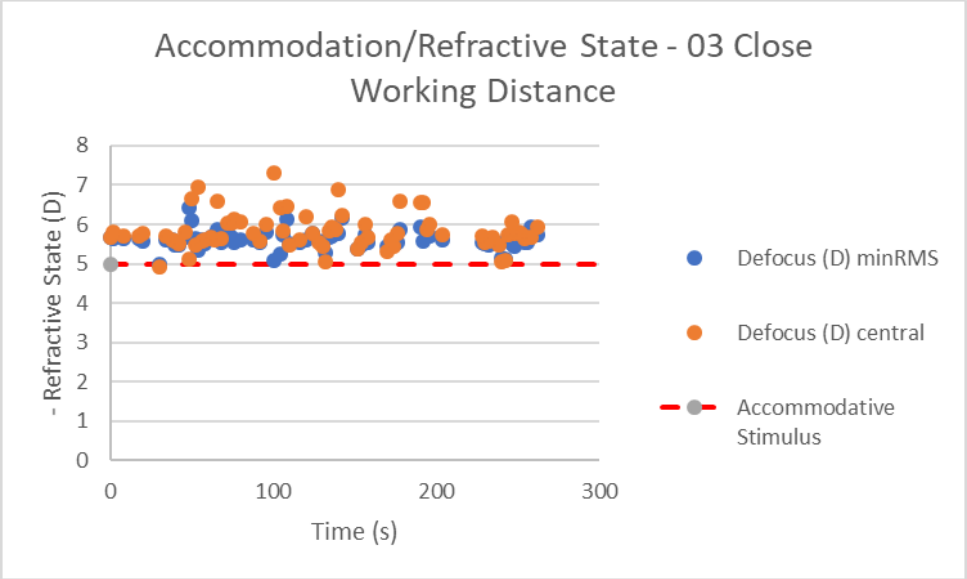
Graph 3.2b

Participant 03 Monocular Baseline Refractive State versus Time



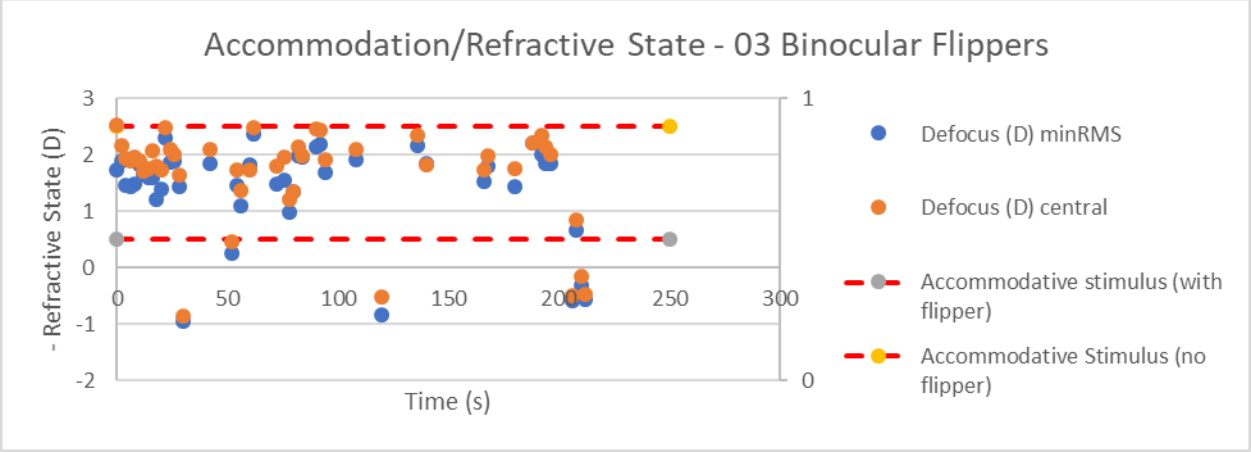
Graph 3.2c

Participant 03 Close Working Distance Refractive State versus Time



Graph 3.2d

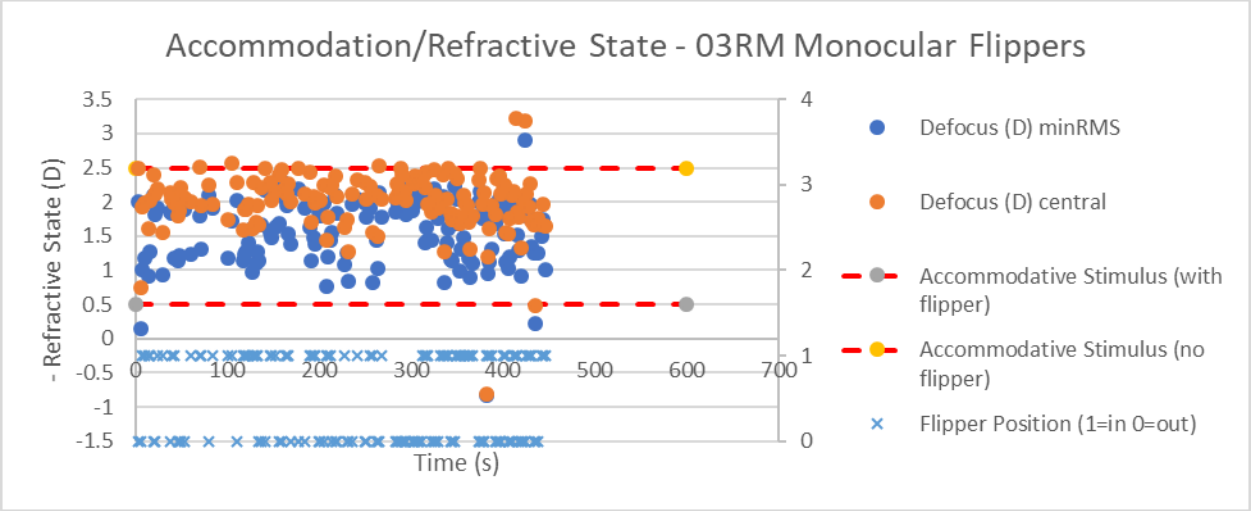
Participant 03 Binocular Flippers Refractive State versus Time



The location of the flippers (in or out) for participant 3 is data missing at random. The video recording file used to determine flipper location was not saved after this trial.

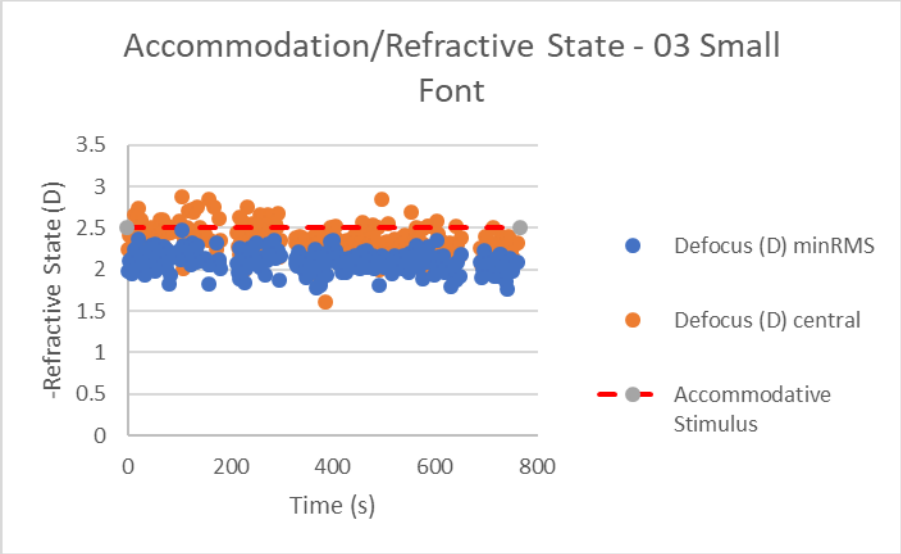
Graph 3.2e

Participant 03 Monocular Flippers Refractive State versus Time



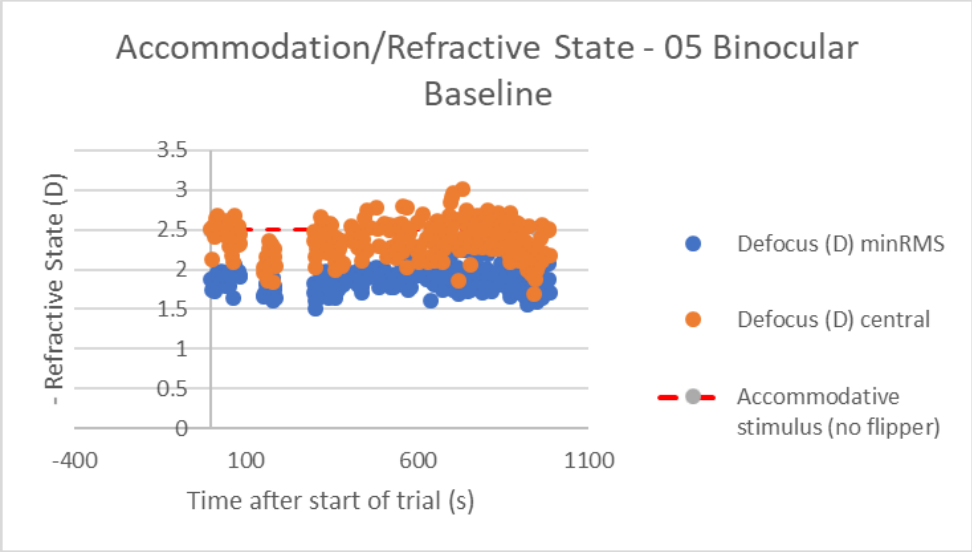
Graph 3.2f

Participant 03 Small Font Refractive State versus Time



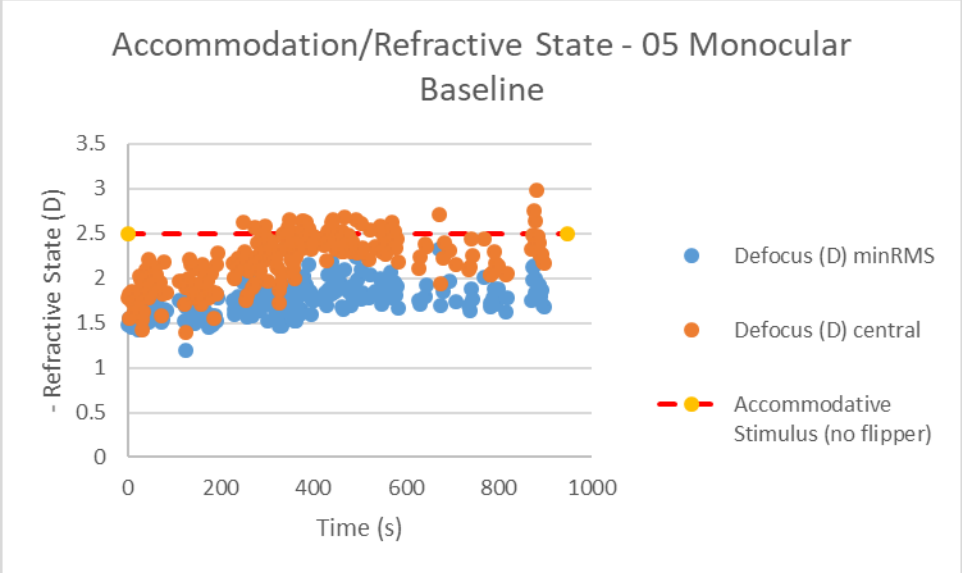
Graph 3.3a

Participant 05 Binocular Baseline Refractive State versus Time



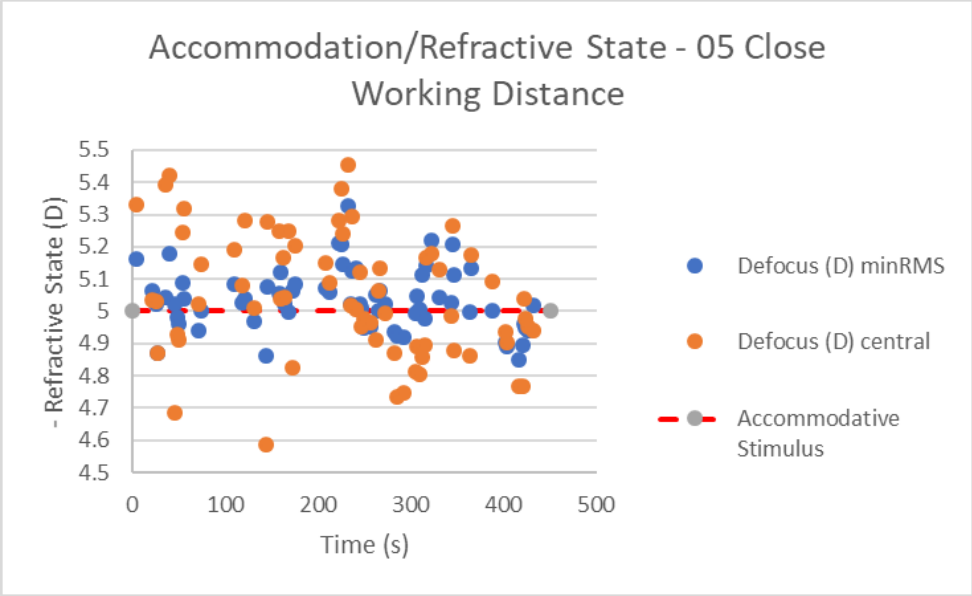
Graph 3.3b

Participant 05 Monocular Baseline Refractive State versus Time



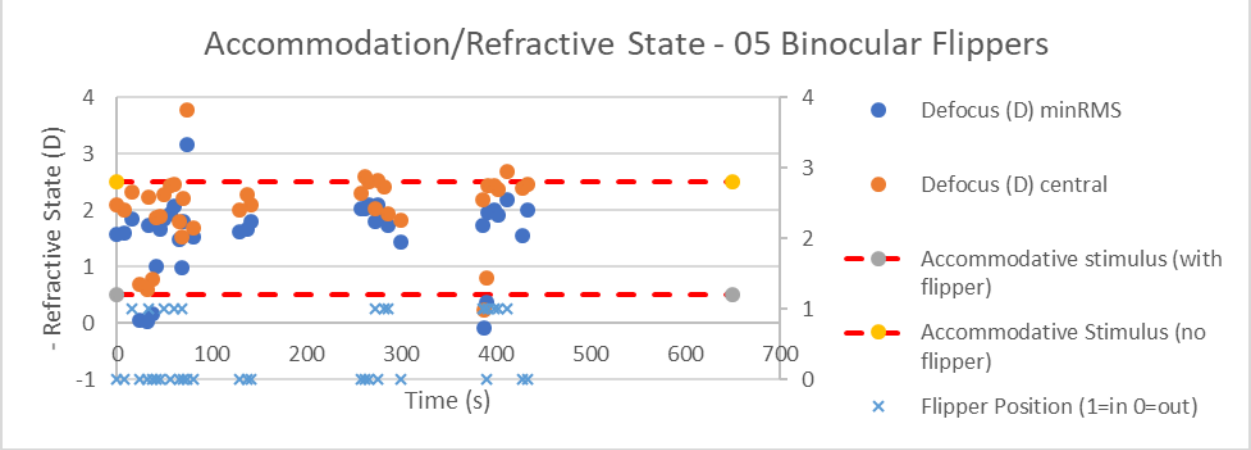
Graph 3.3c

Participant 05 Close Working Distance Refractive State versus Time



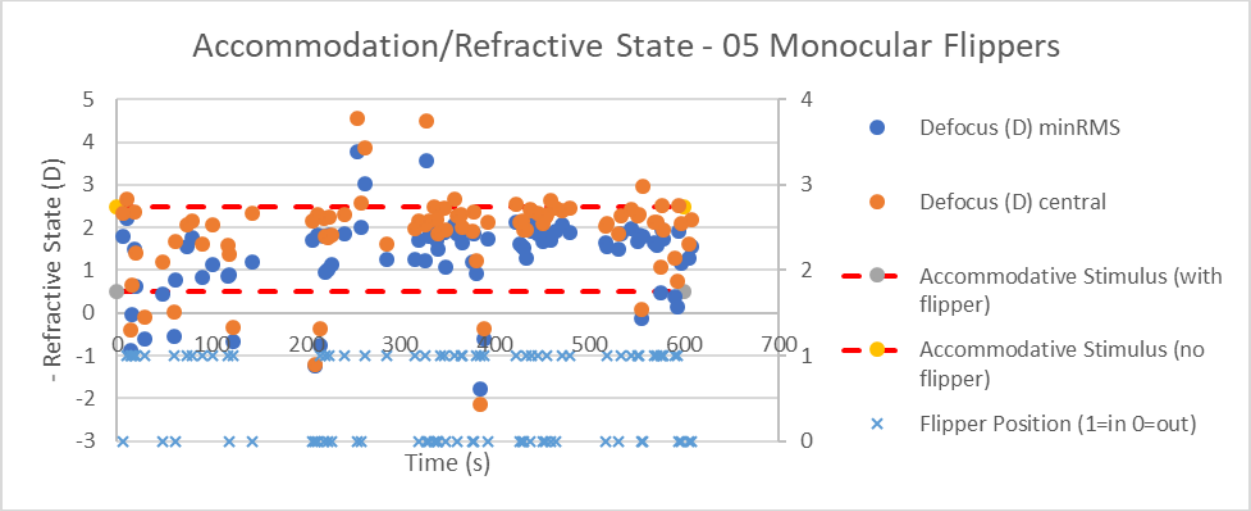
Graph 3.3d

Participant 05 Binocular Flippers Refractive State versus Time



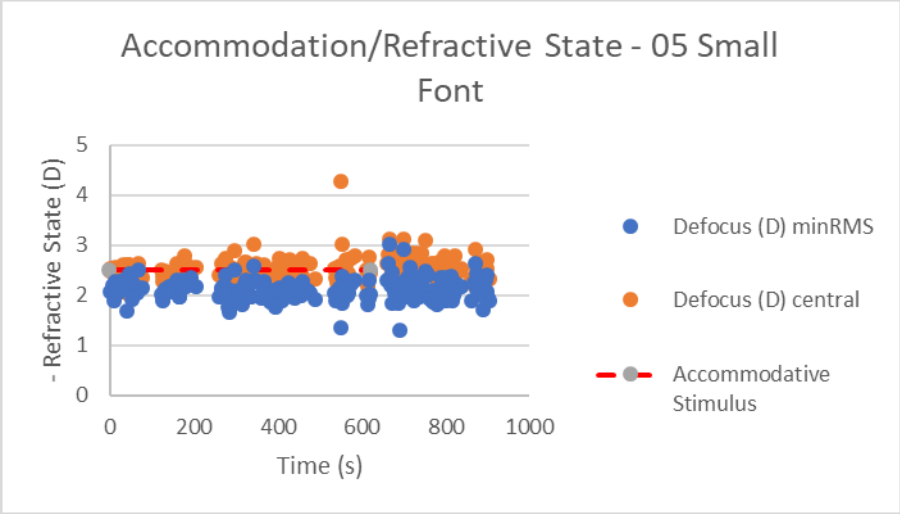
Graph 3.3e

Participant 05 Monocular Flippers Refractive State versus Time



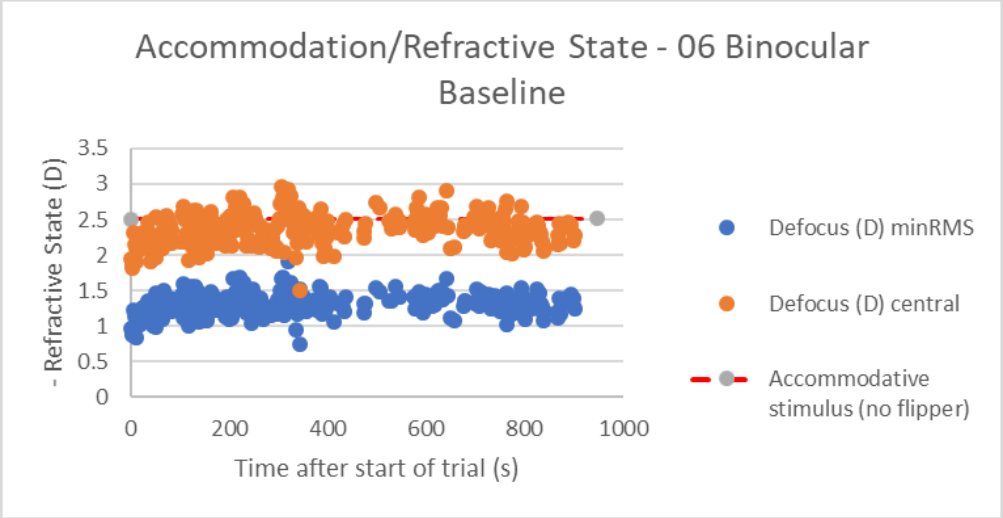
Graph 3.3f

Participant 05 Small Font Refractive State versus Time



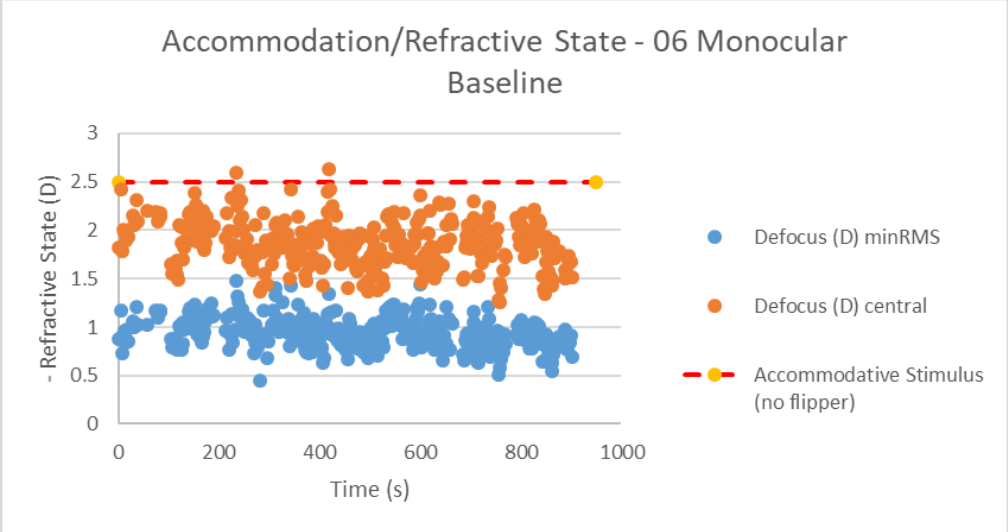
Graph 3.4a

Participant 06 Binocular Baseline Refractive State versus Time



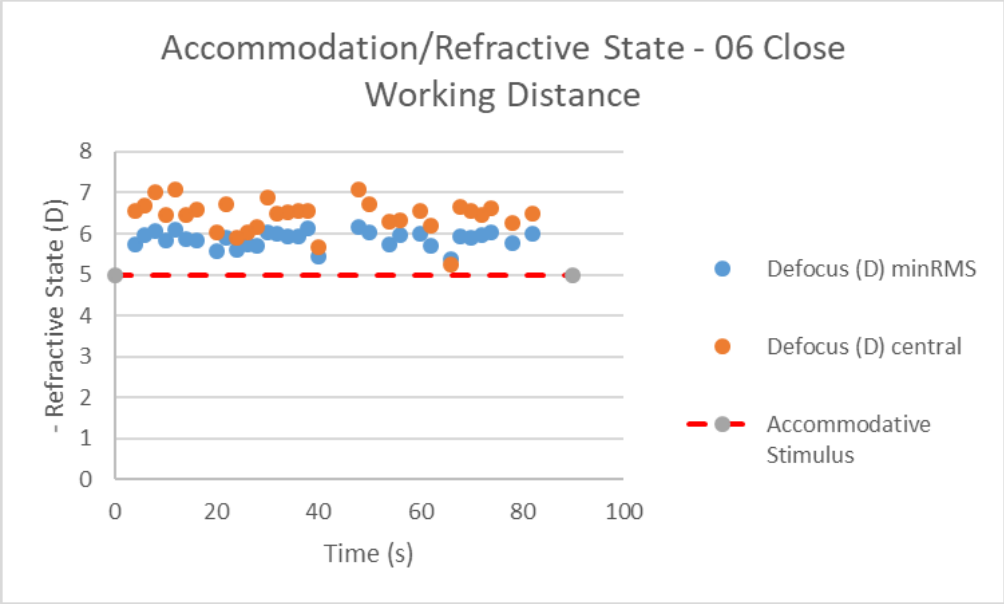
Graph 3.4b

Participant 06 Monocular Baseline Refractive State versus Time



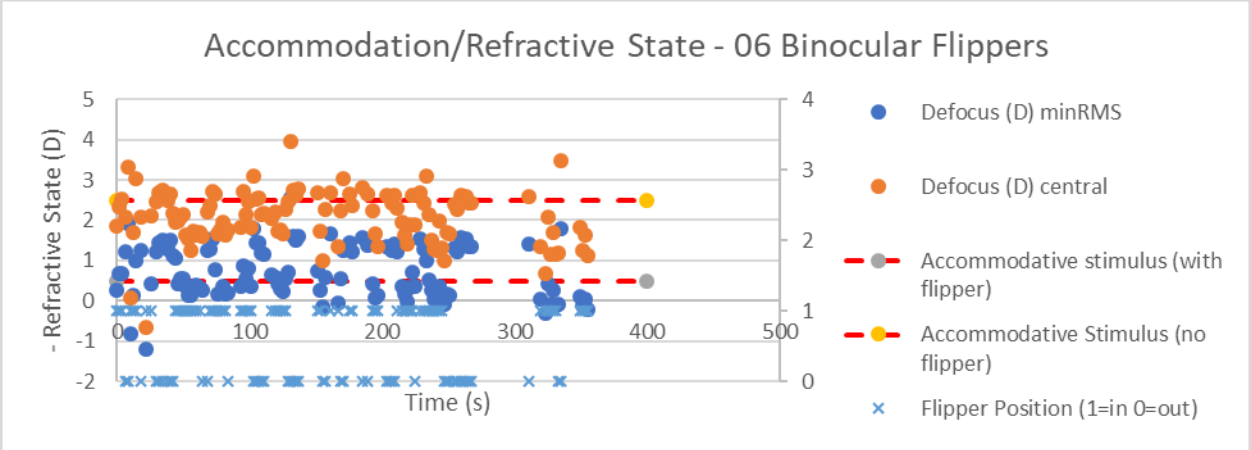
Graph 3.4c

Participant 06 Close Working Distance Refractive State versus Time



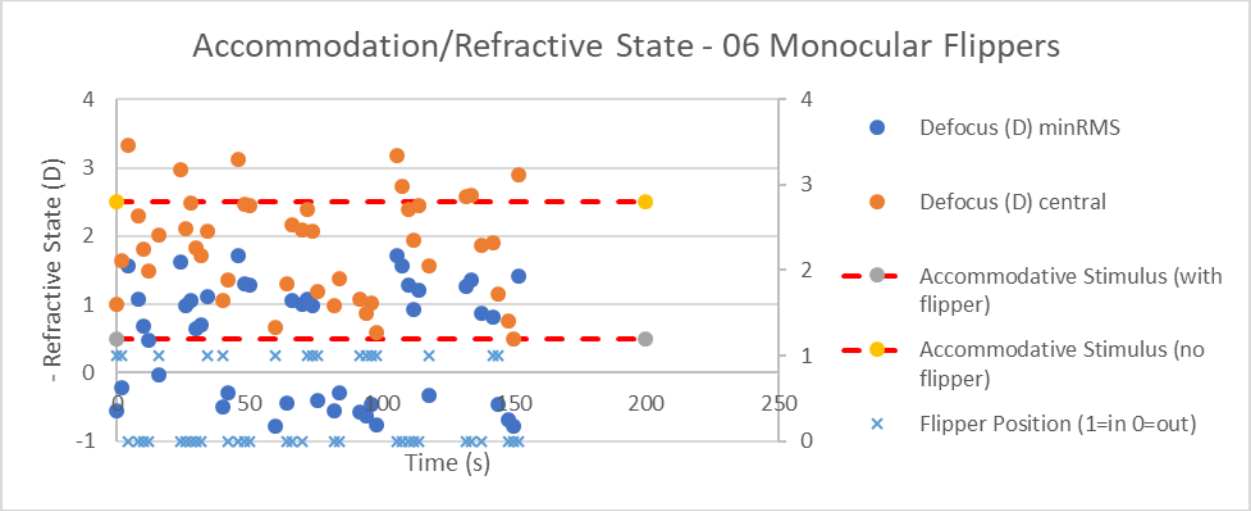
Graph 3.4d

Participant 06 Binocular Flippers Refractive State versus Time



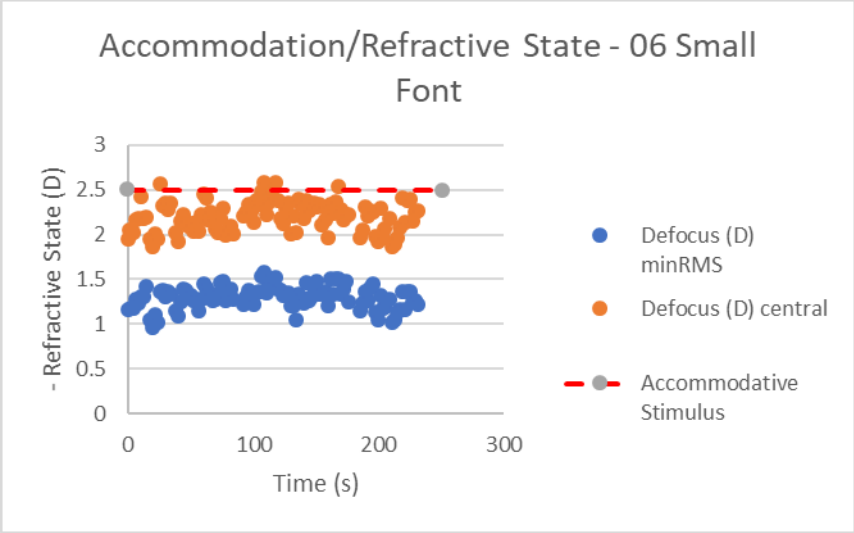
Graph 3.4e

Participant 06 Monocular Flippers Refractive State versus Time



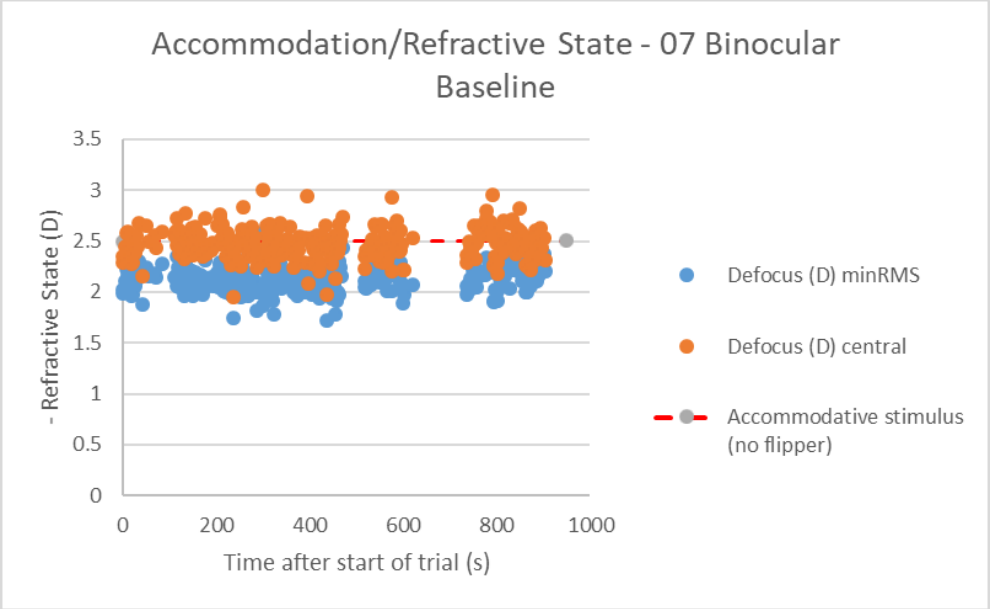
Graph 3.4f

Participant 06 Small Font Refractive State versus Time



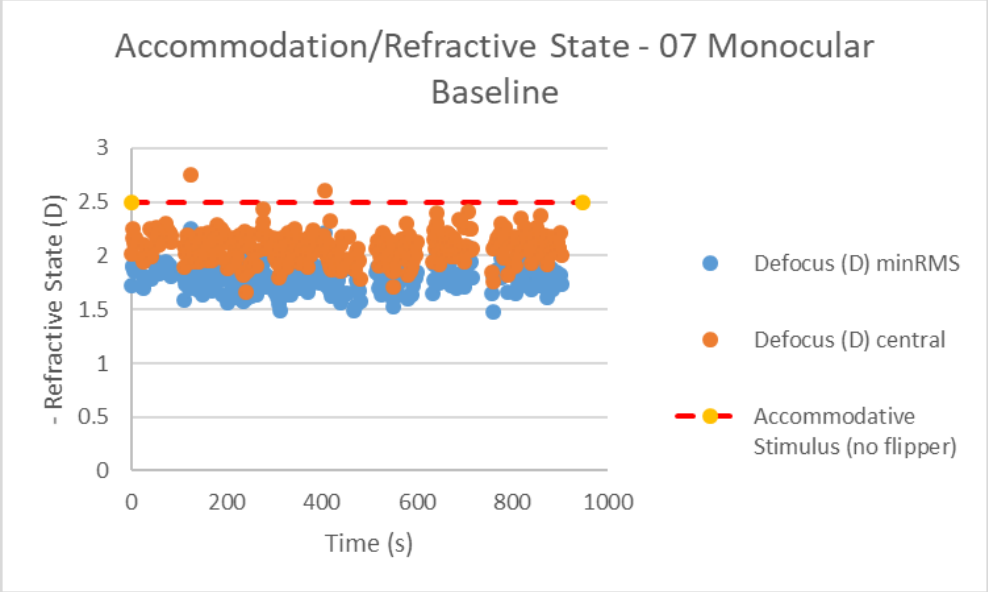
Graph 3.5a

Participant 07 Binocular Baseline Refractive State versus Time



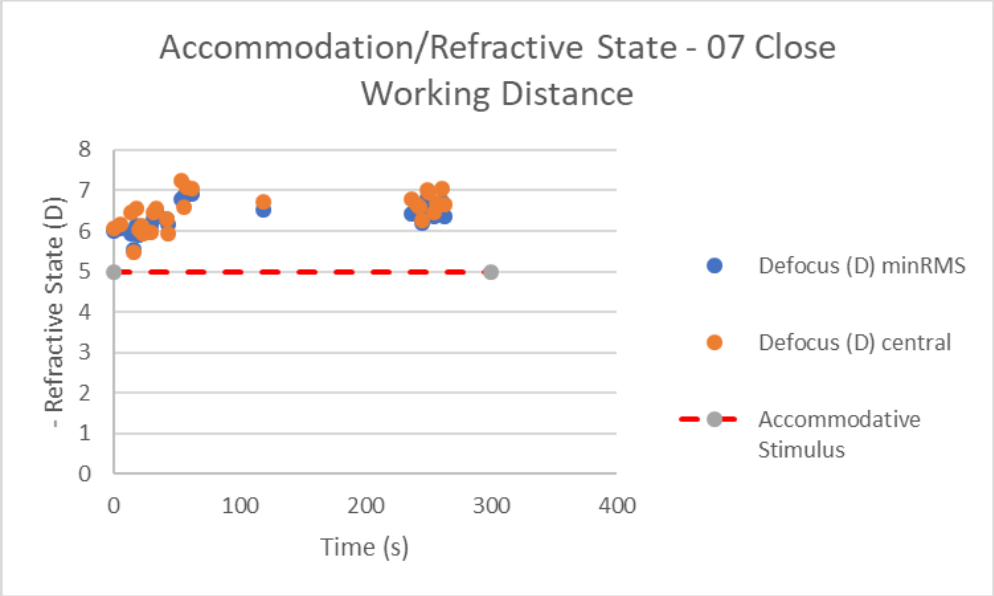
Graph 3.5b

Participant 07 Monocular Baseline Refractive State versus Time



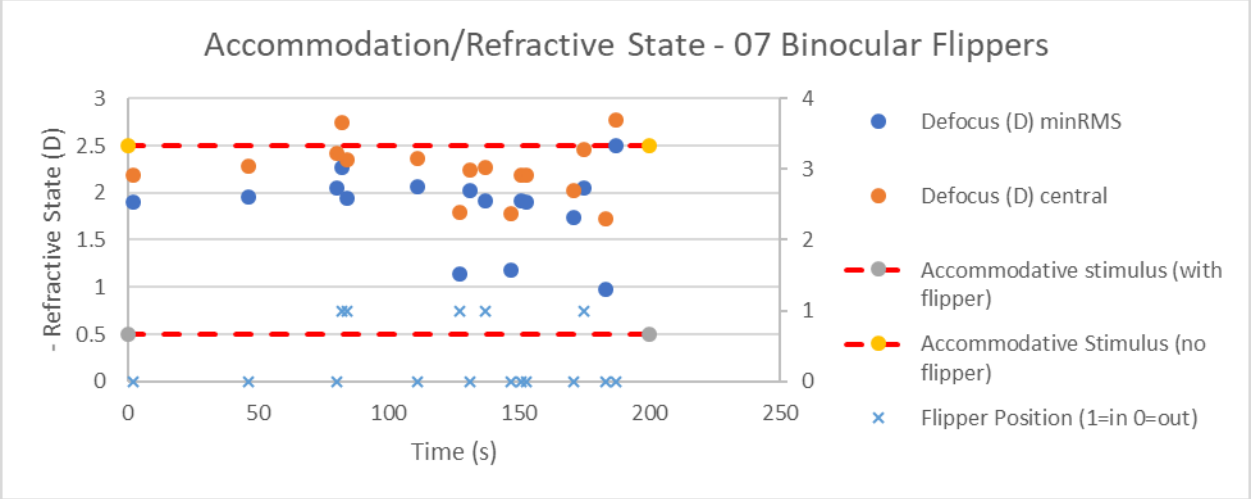
Graph 3.5c

Participant 07 Close Working Distance Refractive State versus Time



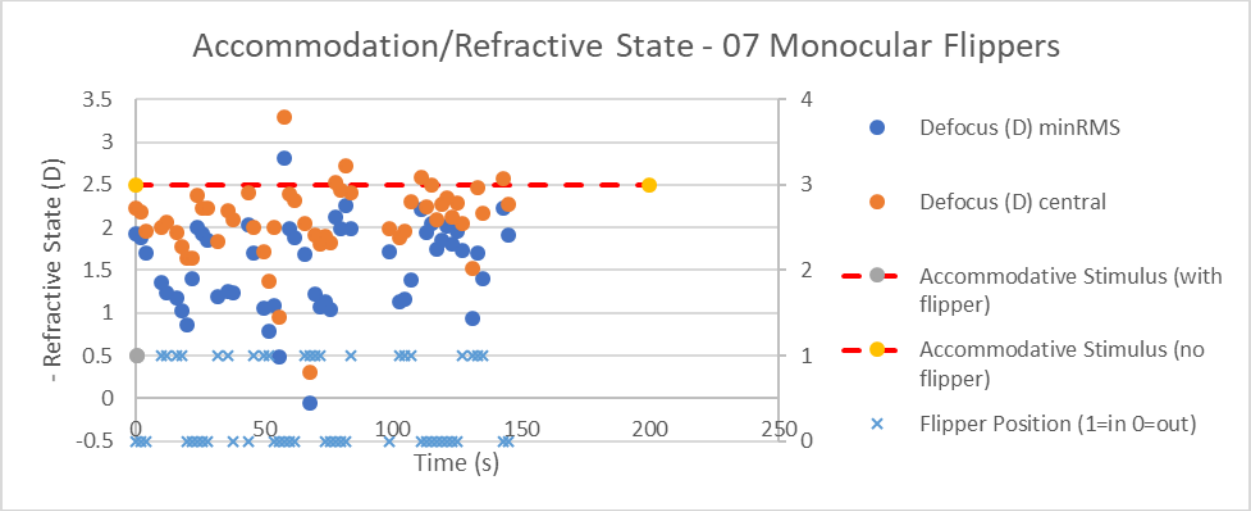
Graph 3.5d

Participant 07 Binocular Flippers Refractive State versus Time



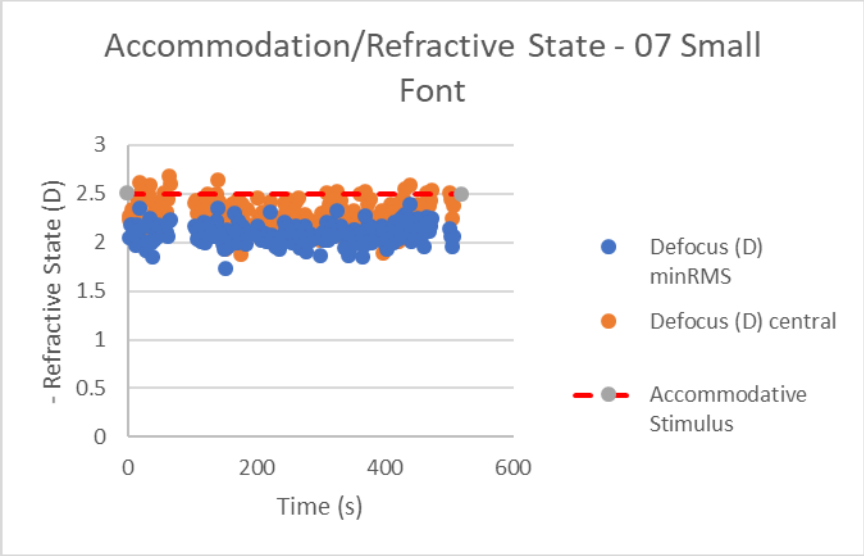
Graph 3.5e

Participant 07 Monocular Flippers Refractive State versus Time



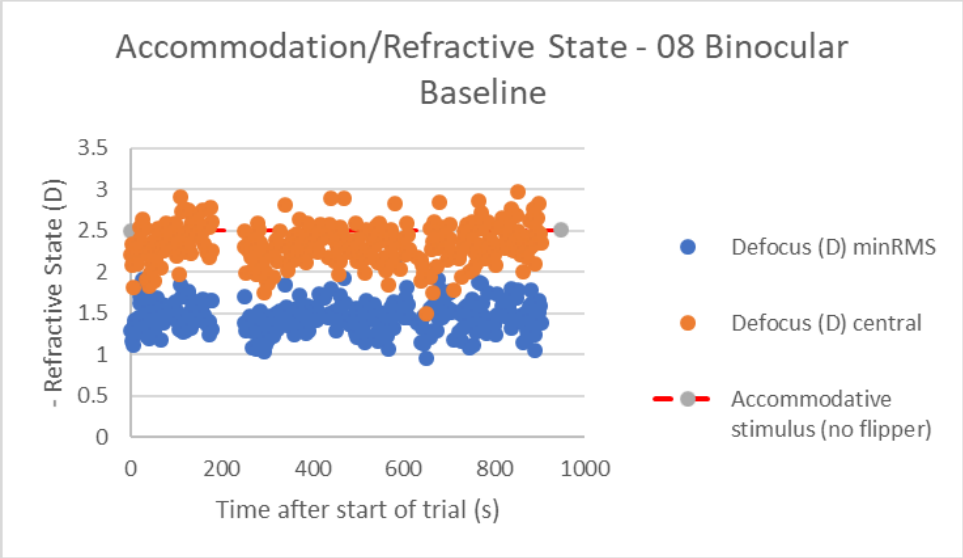
Graph 3.5f

Participant 07 Small Font Refractive State versus Time



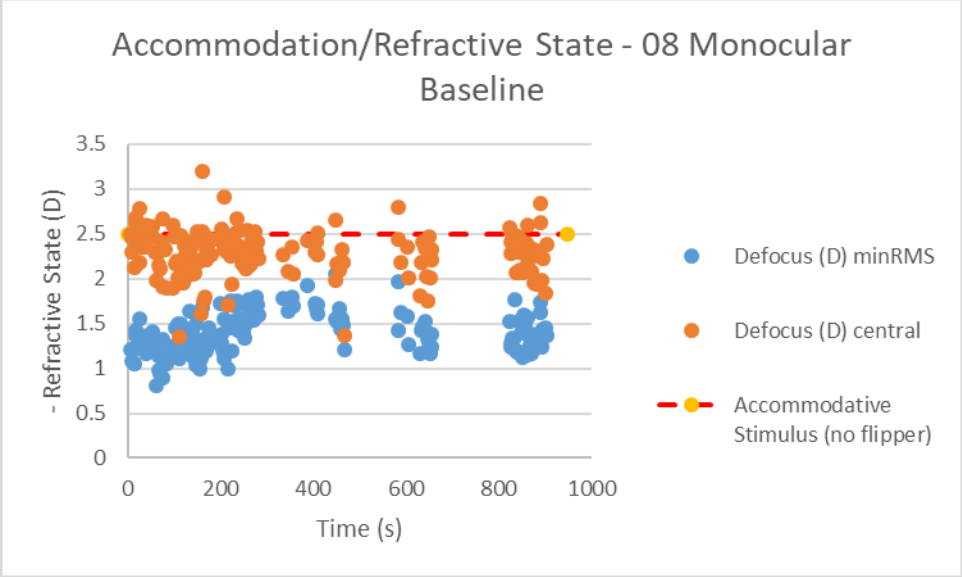
Graph 3.6a

Participant 08 Binocular Baseline Refractive State versus Time



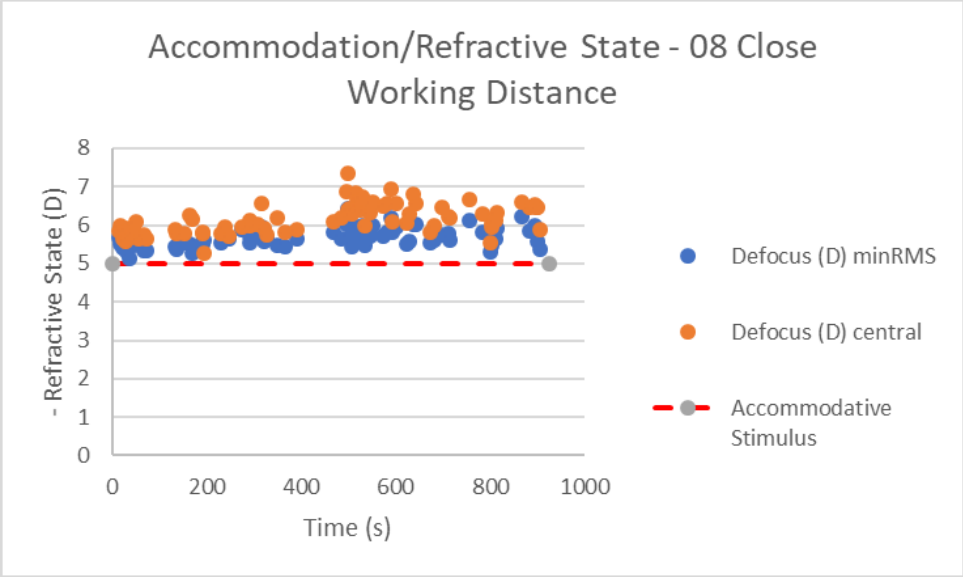
Graph 3.6b

Participant 08 Monocular Baseline Refractive State versus Time



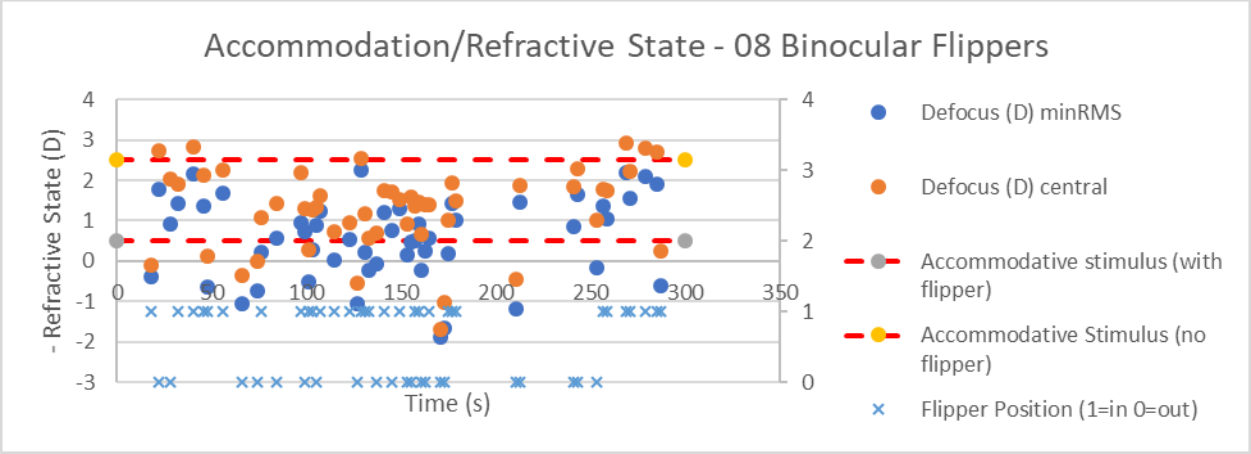
Graph 3.6c

Participant 08 Close Working Distance Refractive State versus Time



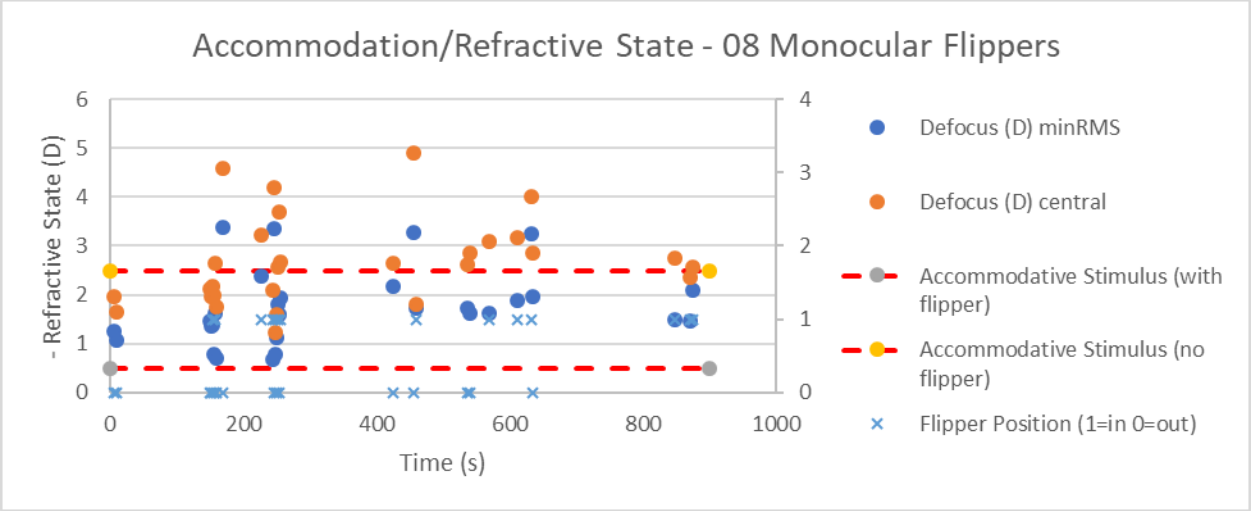
Graph 3.6d

Participant 08 Binocular Flippers Refractive State versus Time



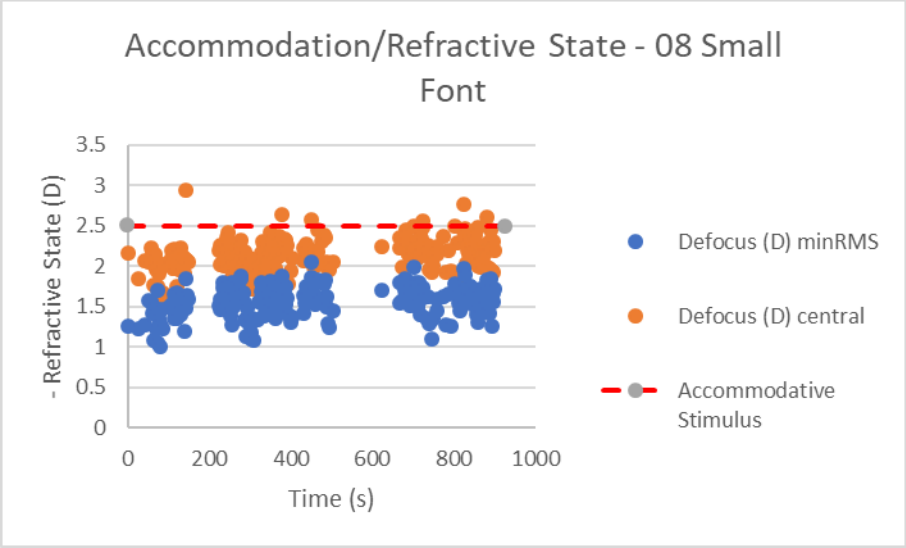
Graph 3.6e

Participant 08 Monocular Flippers Refractive State versus Time



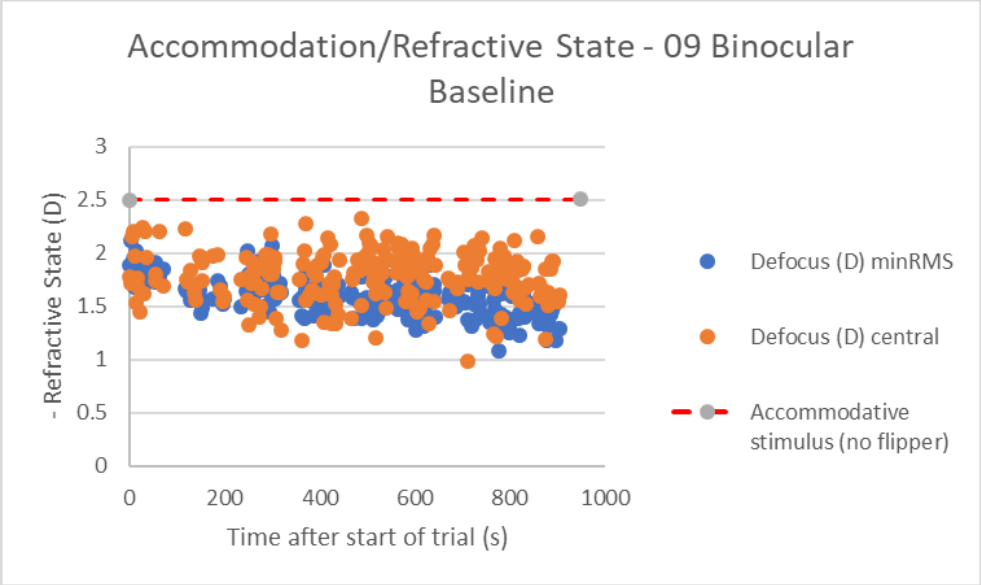
Graph 3.6f

Participant 08 Small Font Refractive State versus Time



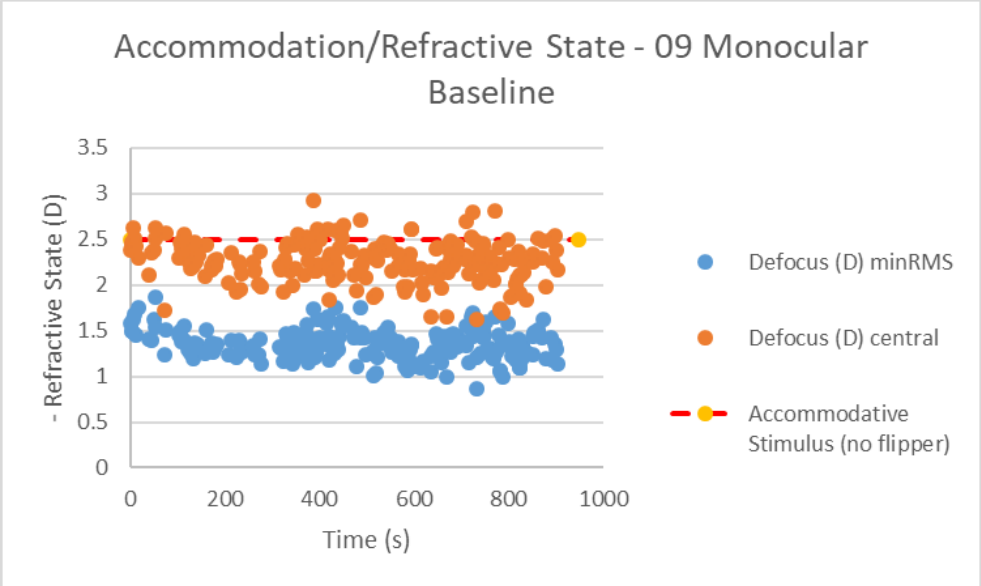
Graph 3.7a

Participant 09 Binocular Baseline Refractive State versus Time



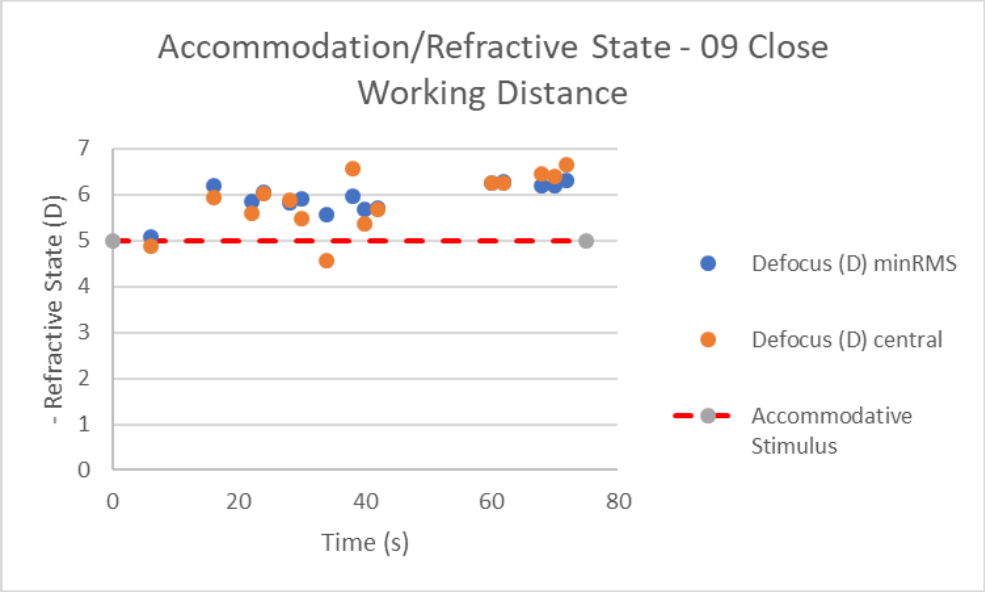
Graph 3.7b

Participant 09 Monocular Baseline Refractive State versus Time



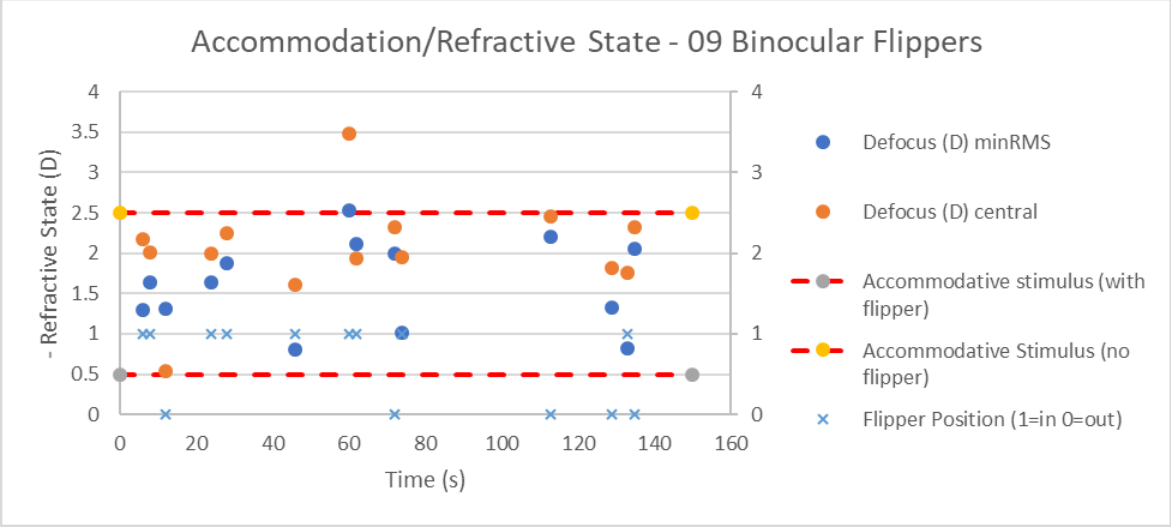
Graph 3.7c

Participant 09 Close Working Distance Refractive State versus Time



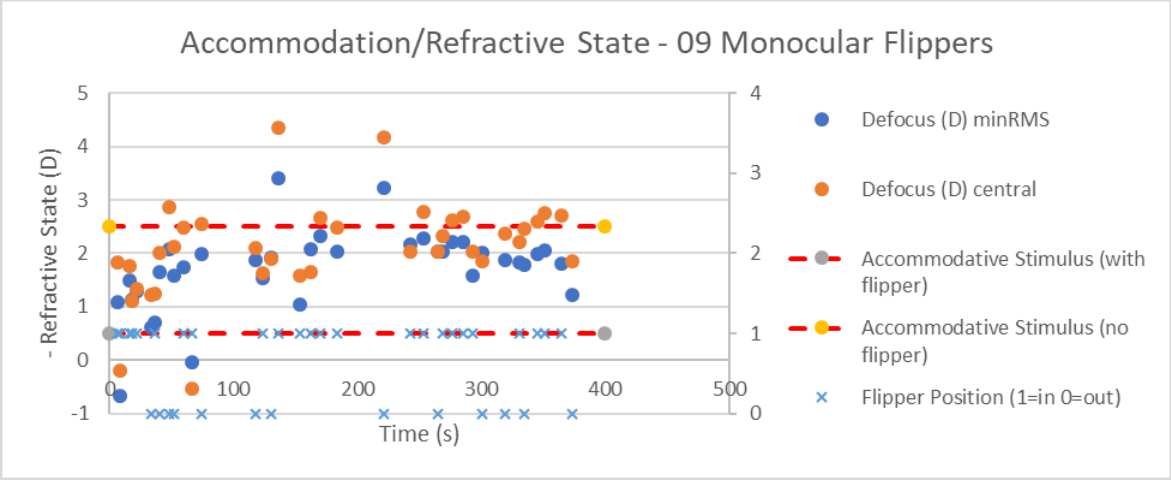
Graph 3.7d

Participant 09 Binocular Flippers Refractive State versus Time



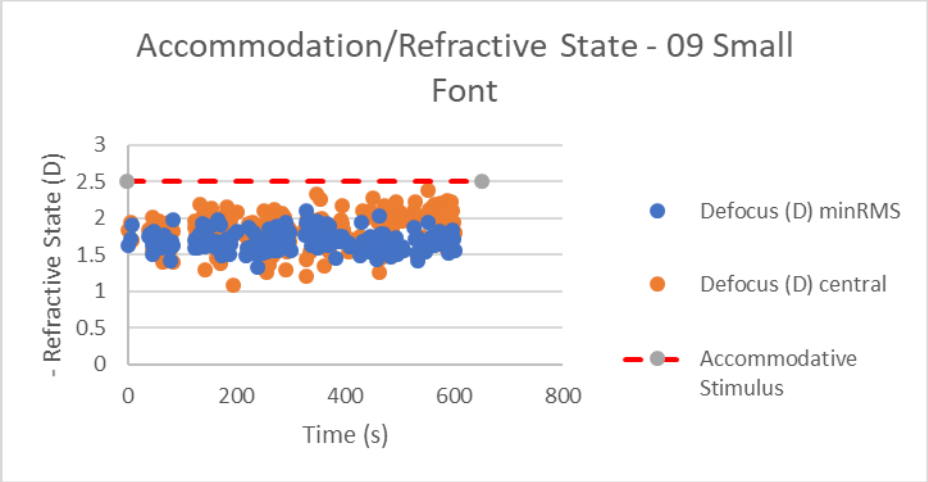
Graph 3.7e

Participant 09 Monocular Flippers Refractive State versus Time



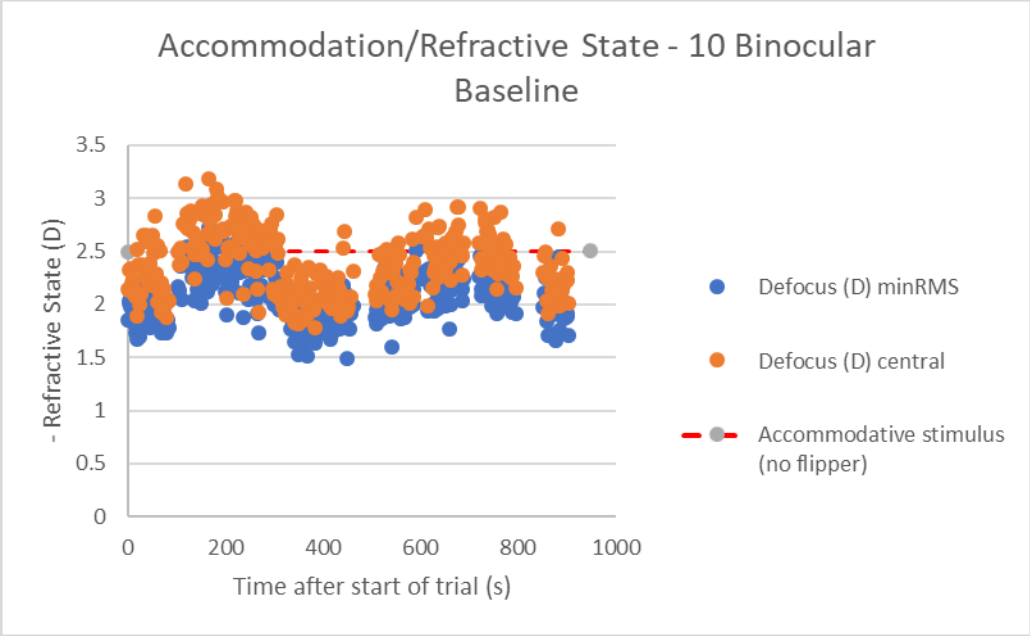
Graph 3.7f

Participant 09 Small Font Refractive State versus Time



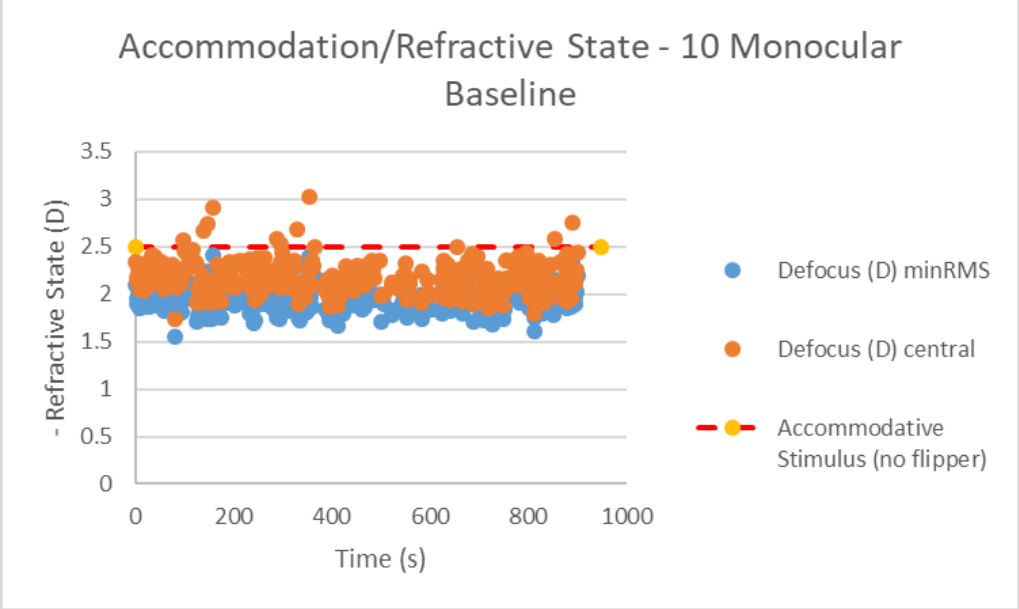
Graph 3.8a

Participant 10 Binocular Baseline Refractive State versus Time



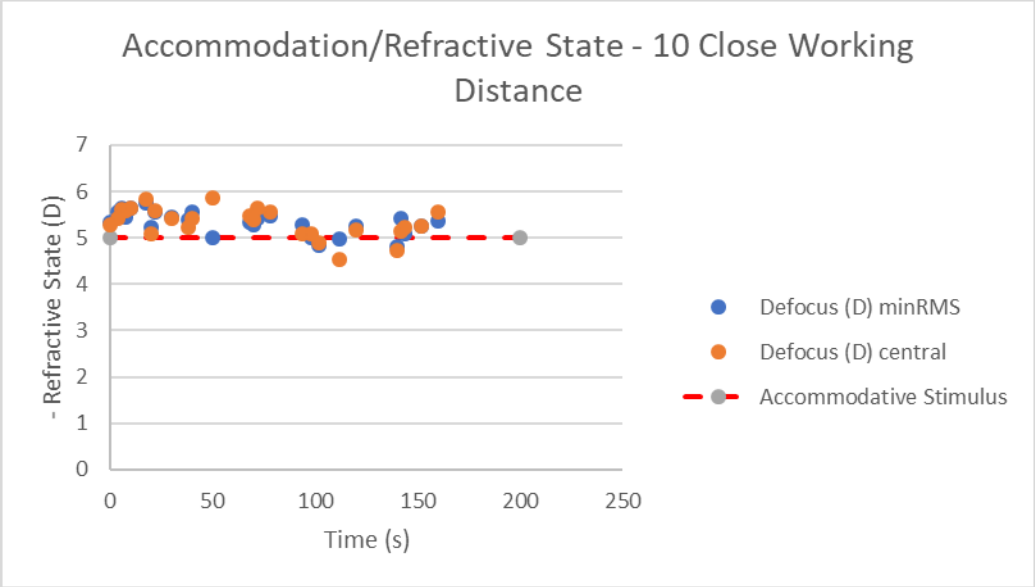
Graph 3.8b

Participant 10 Monocular Baseline Refractive State versus Time



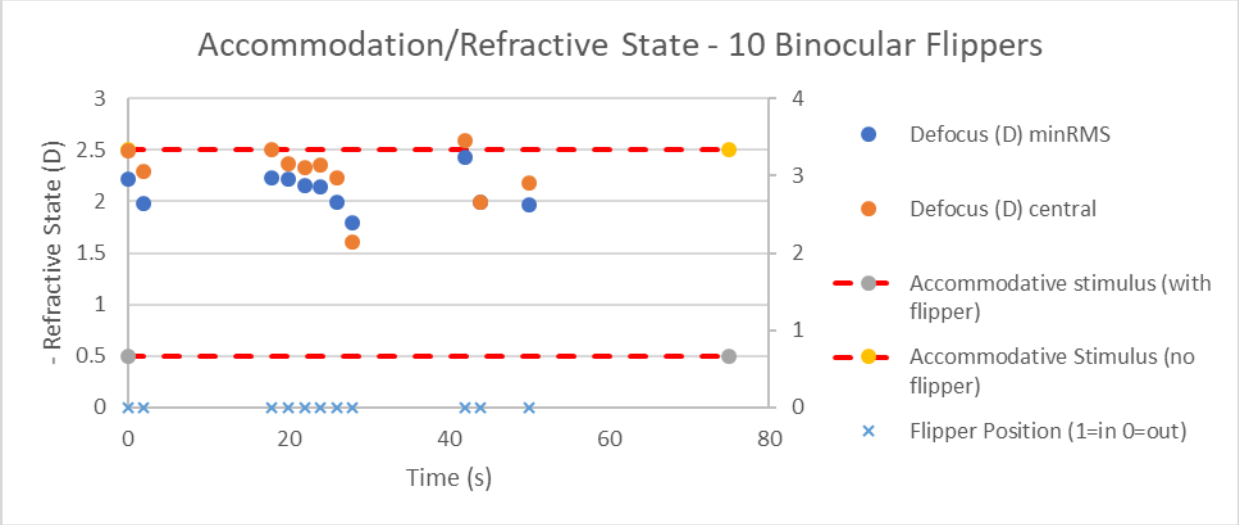
Graph 3.8c

Participant 10 Close Working Distance Refractive State versus Time



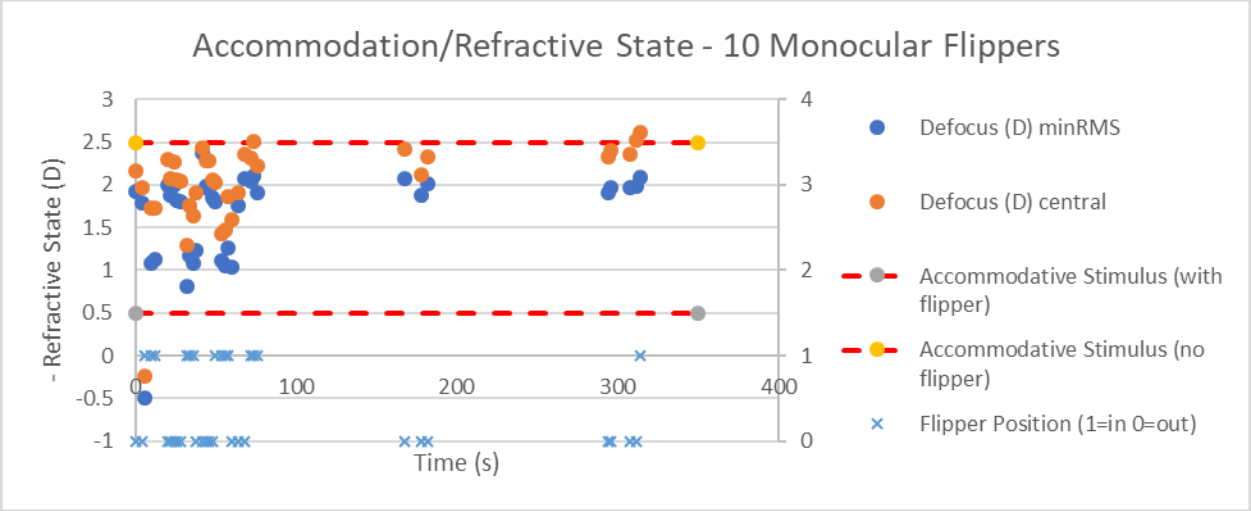
Graph 3.8d

Participant 10 Binocular Flippers Refractive State versus Time



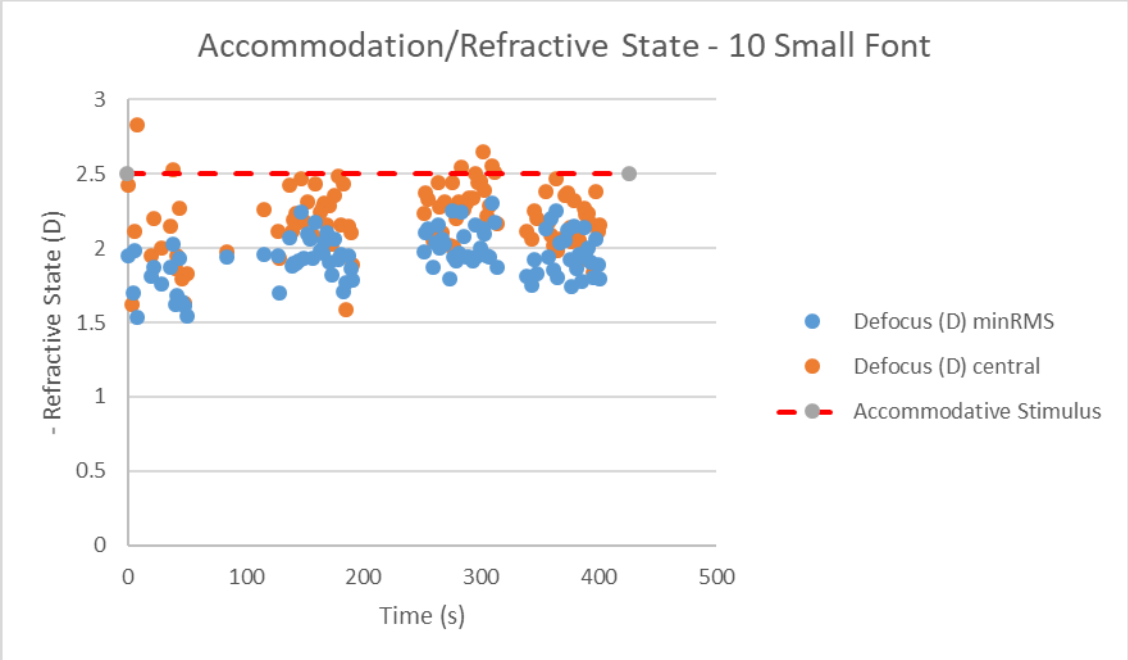
Graph 3.8e

Participant 10 Monocular Flippers Refractive State versus Time



Graph 3.8f

Participant 10 Small Font Refractive State versus Time

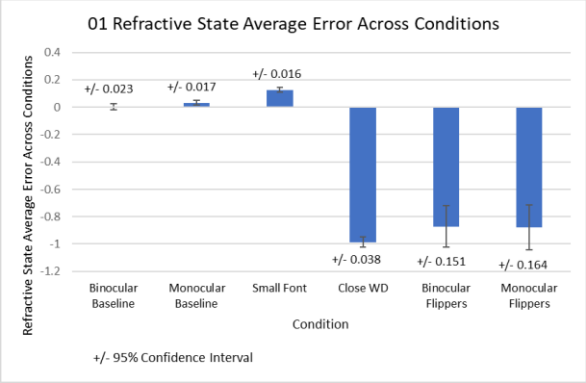


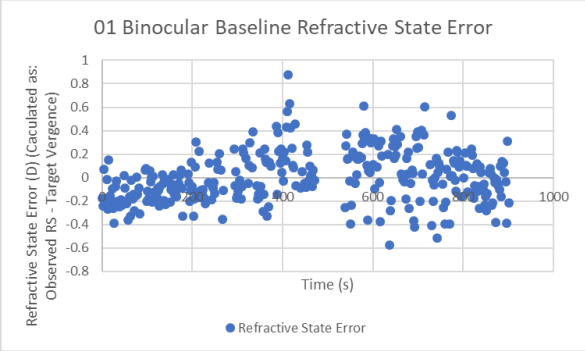
In summary, the preceding graphs (3.1a-f through 3.8a-f) reveal each participant's accommodative lag by measuring their respective defocus during each testing duration. A detailed analysis of these results in comparison to that of the expected results of a model eye may be found in the discussion section.

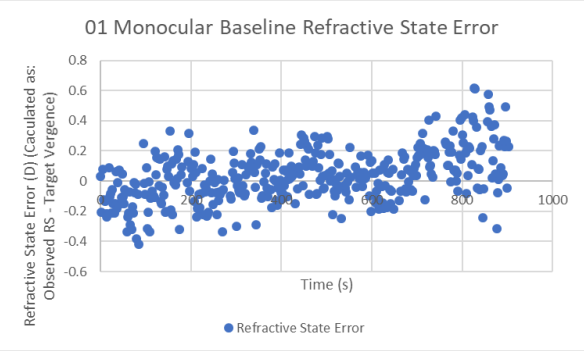
The following graphs further isolate the pertinent refractive state data by focusing on the paraxial (central) refractive state data, as it most closely approximates the participant's true point of focus and is irrespective of pupil size. The refractive state error was calculated at each data point over the time of the trial as the observed refractive state minus the target vergence (due to the accommodative stimulus). The average refractive state error shows the average accommodative lag (positive error) or accommodative lead (negative error). An accommodative lag was seen in all testing conditions except those that involved the addition of a lens in the testing set-up: binocular and monocular flippers with flippers, and the close working distance condition. When analyzed through the COAS aberrometer, the flipper used in the binocular and monocular flippers testing conditions resulted with an appearance of an increase in myopia, thus causing a data output of negative error values. This is seen consistently in each participants' data. The finding that the close working distance condition resulted with negative error as well is more complex, and its analysis is presented in the discussion section.

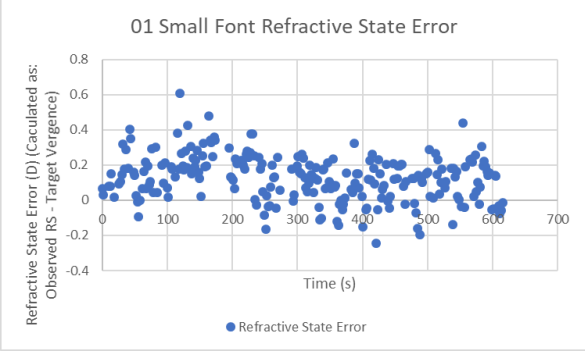
Graph 4.1

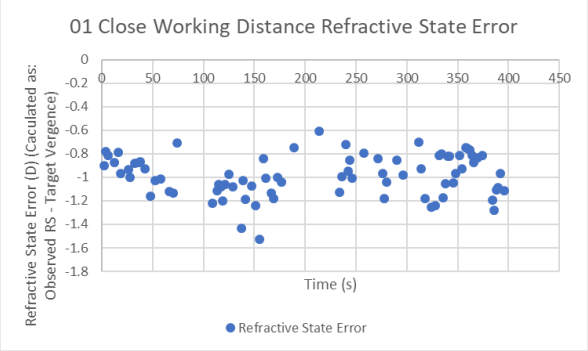
Participant 01 Refractive State Average Error Across Conditions

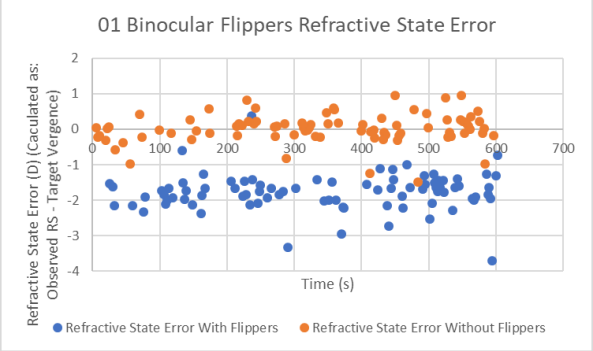


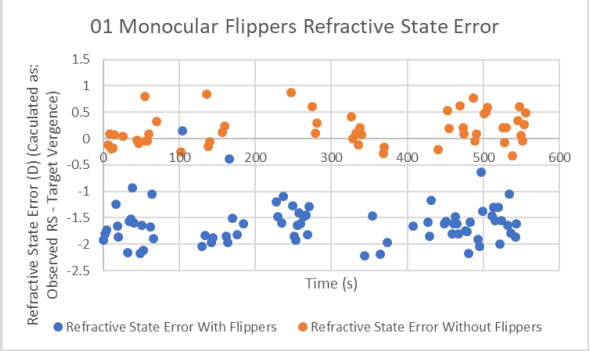






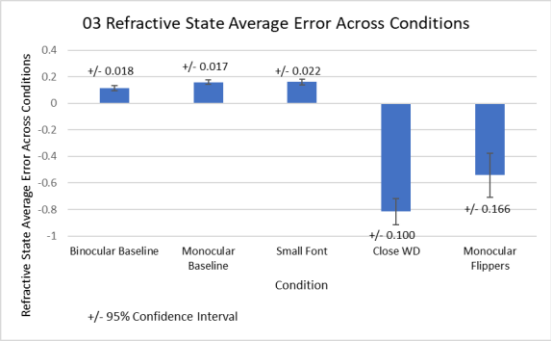


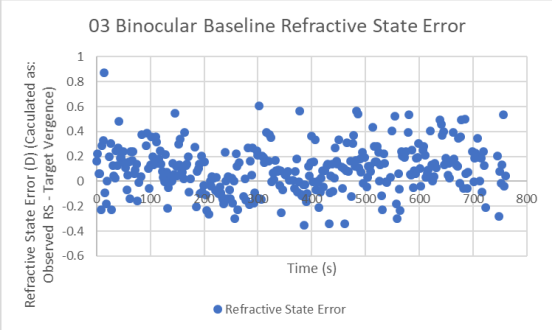


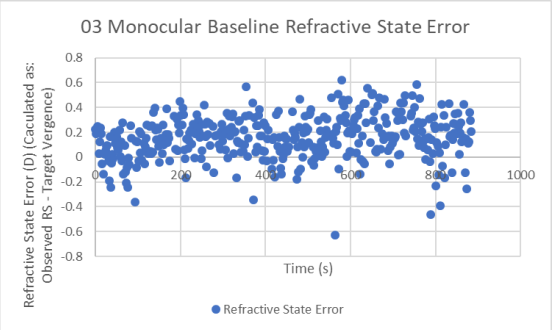


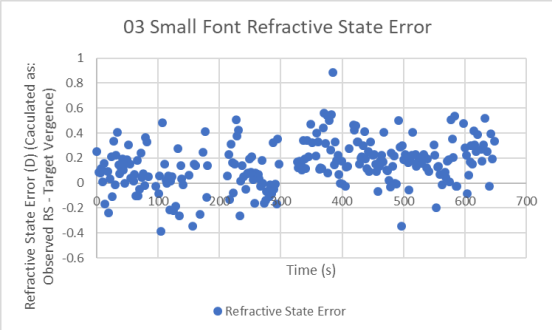
Graph 4.2

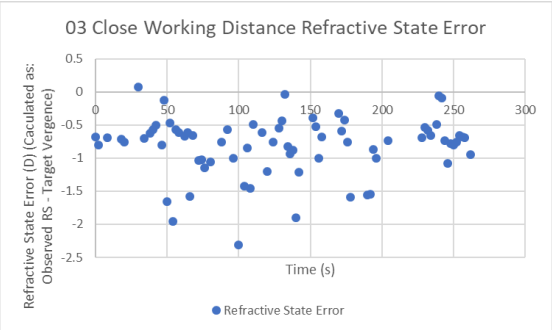
Participant 03 Refractive State Average Error Across Conditions

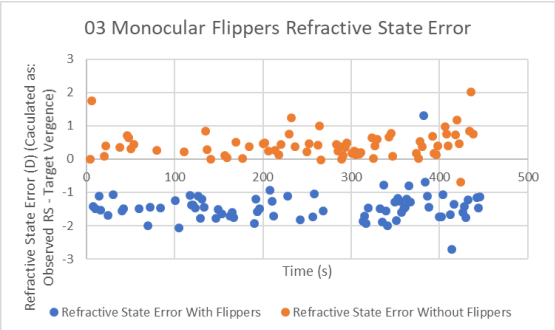








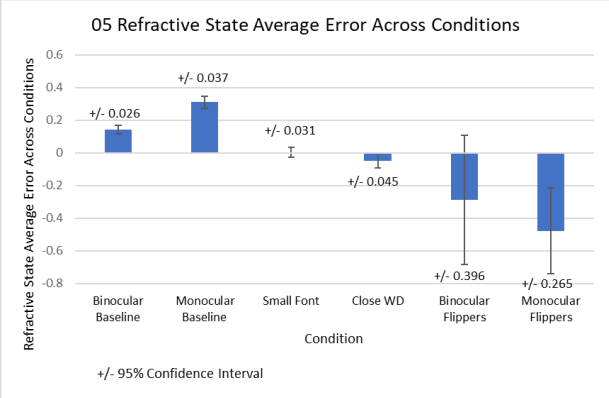


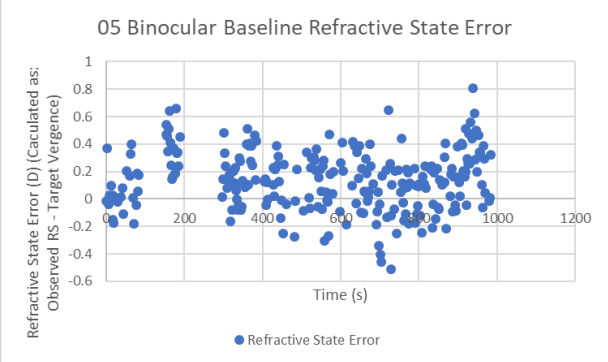


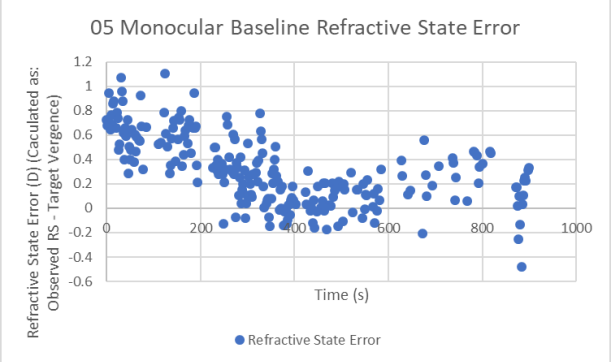
As no video data exists to parse the with- and without-flippers data for the binocular flippers condition for participant 03, no graph was created for that condition.

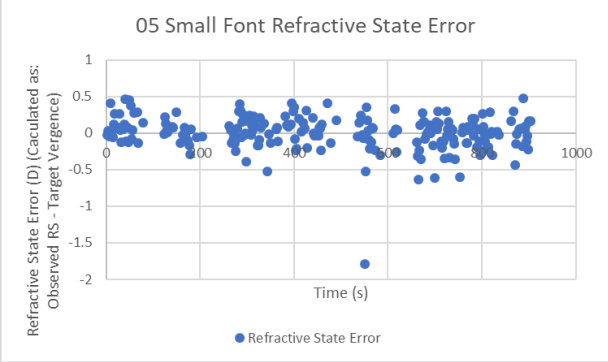
Graph 4.3

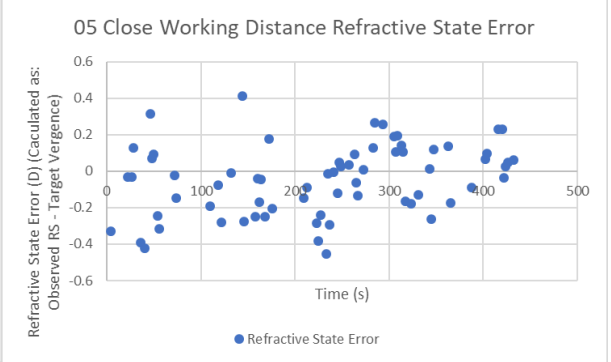
Participant 05 Refractive State Average Error Across Conditions

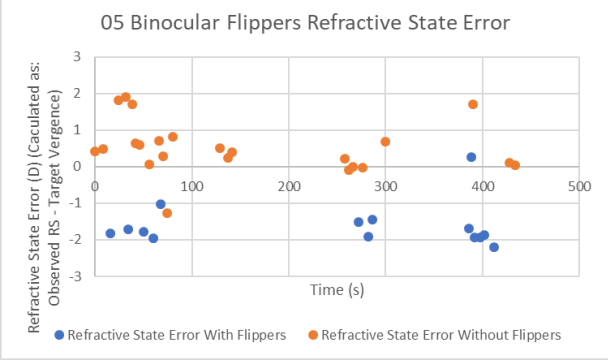


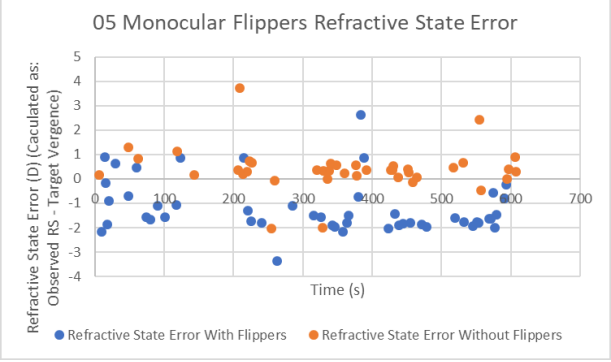






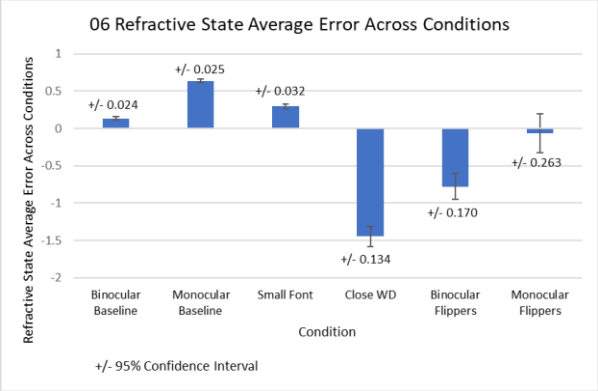


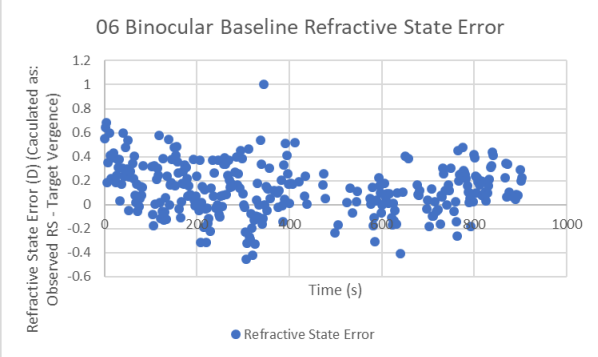


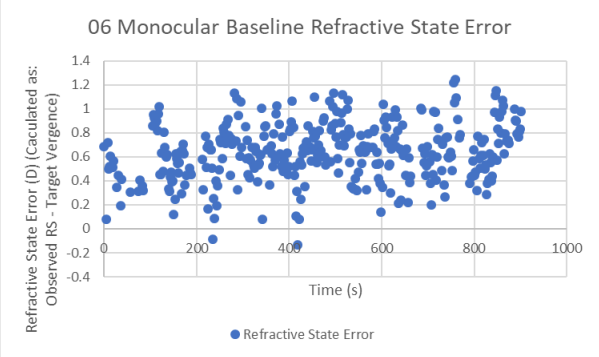


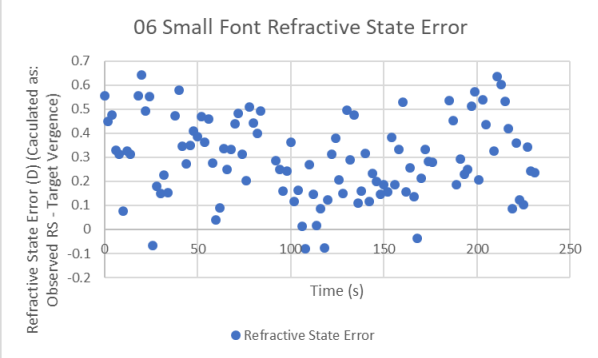
Graph 4.4

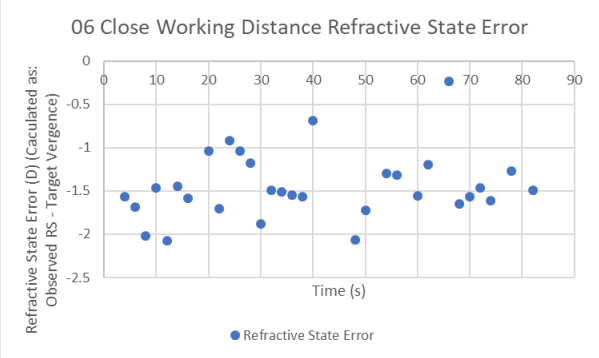
Participant 06 Refractive State Average Error Across Conditions

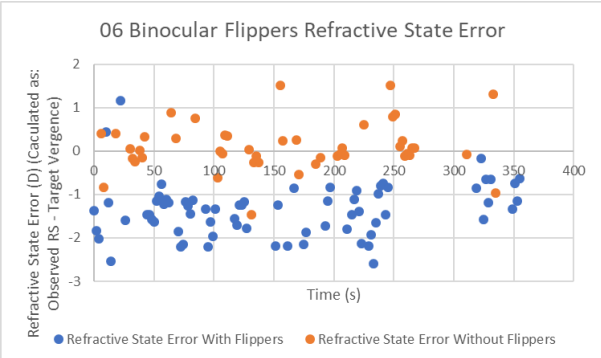


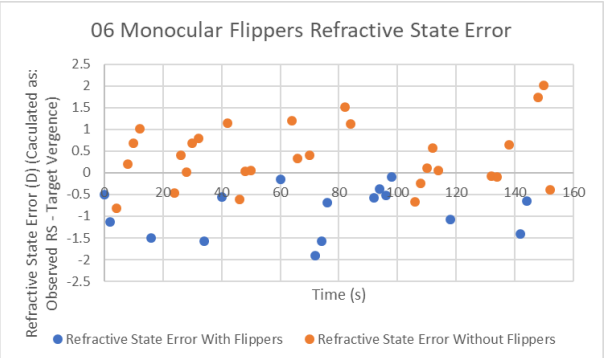






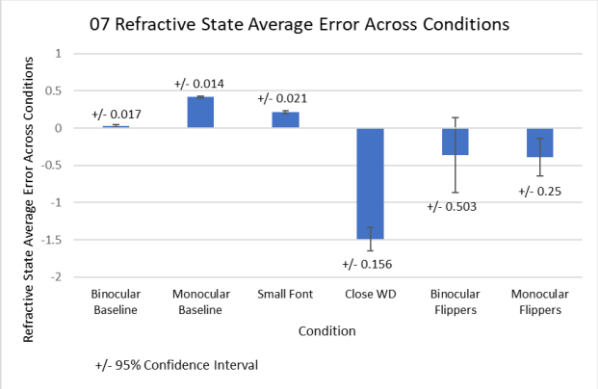


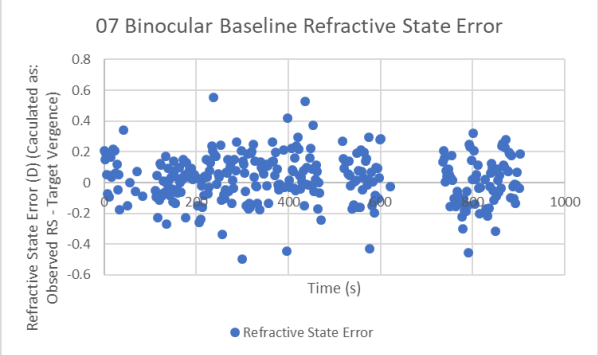


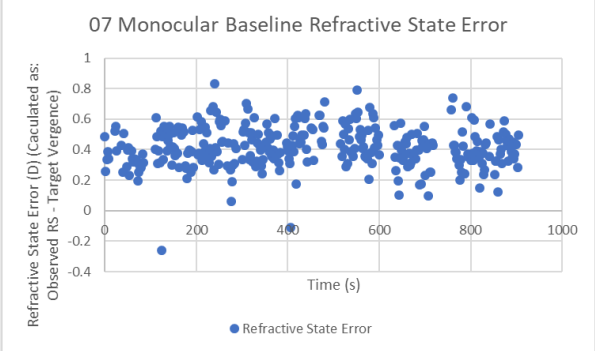


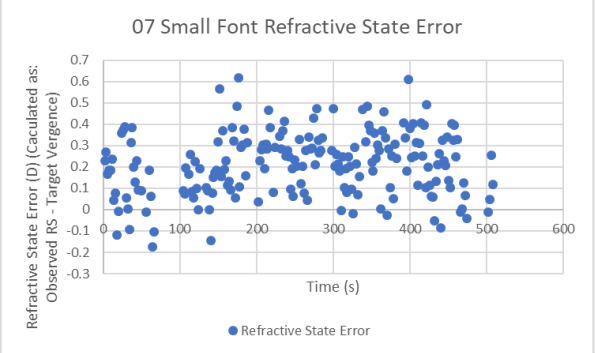
Graph 4.5

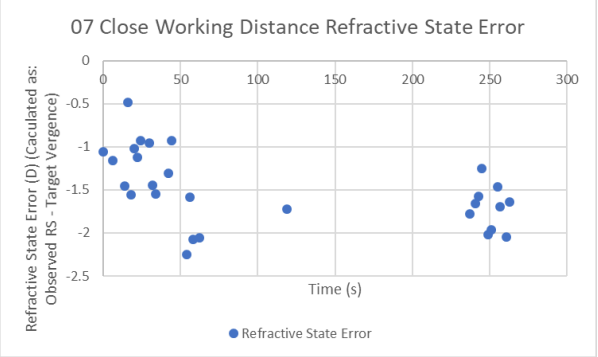
Participant 07 Refractive State Average Error Across Conditions

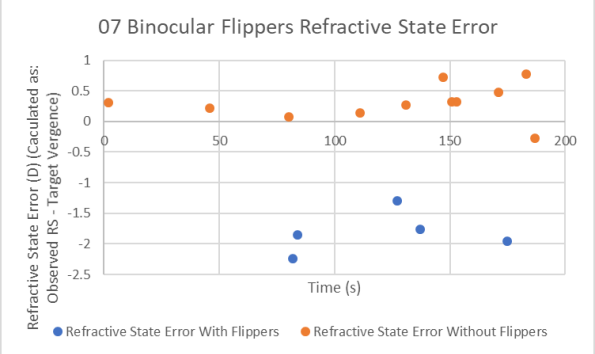


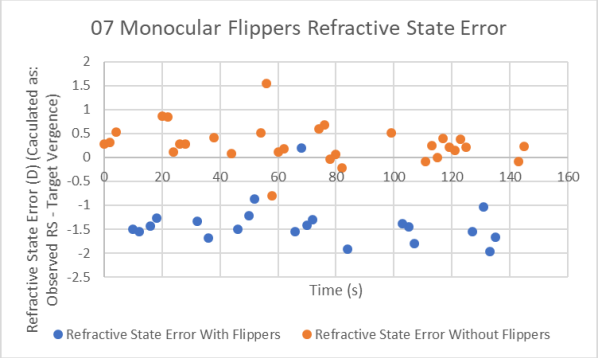






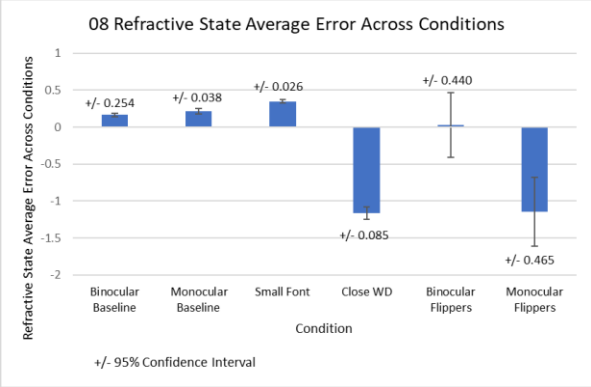


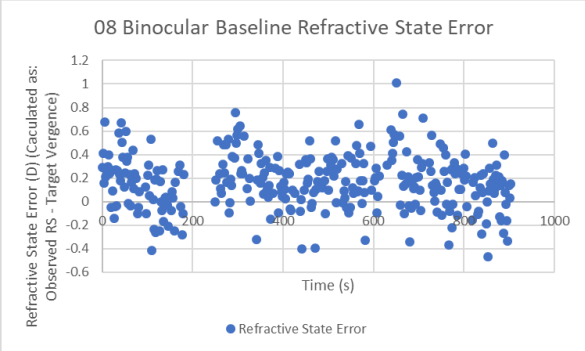


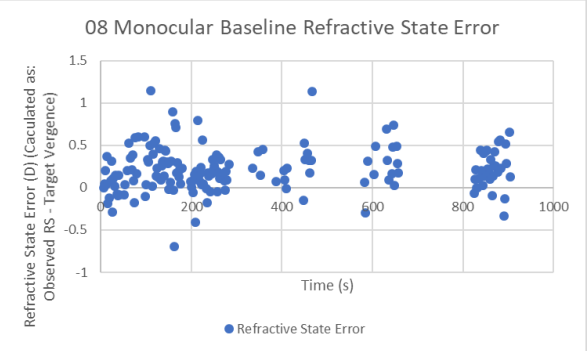


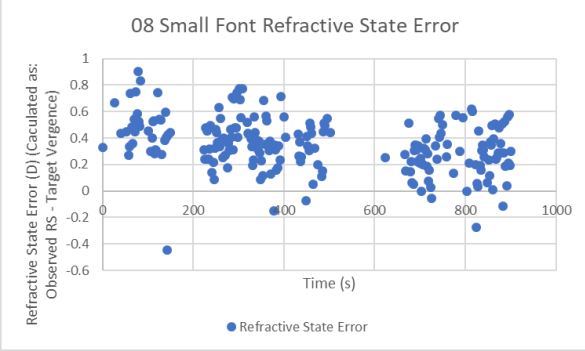
Graph 4.6

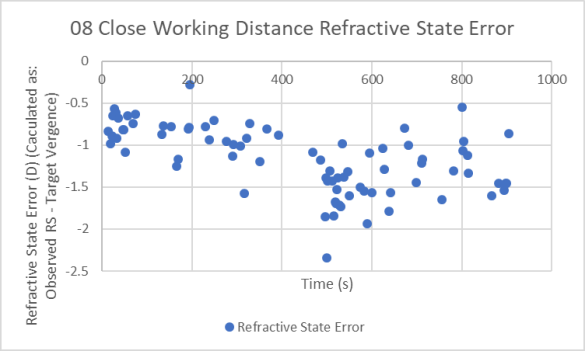
Participant 08 Refractive State Average Error Across Conditions

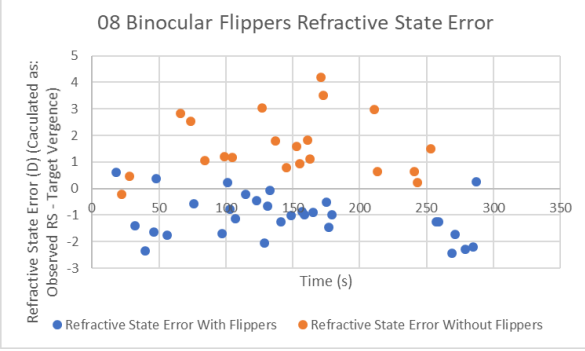


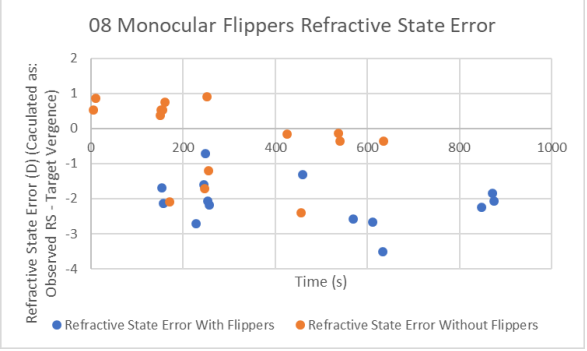






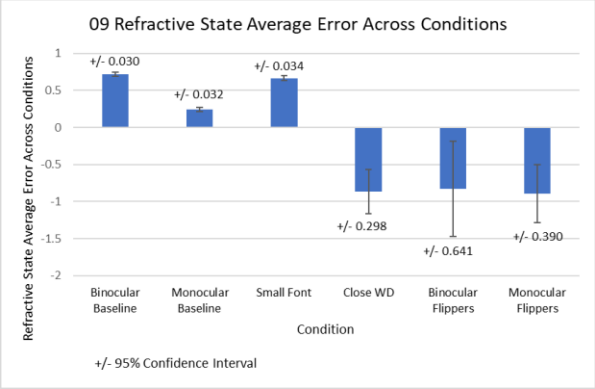


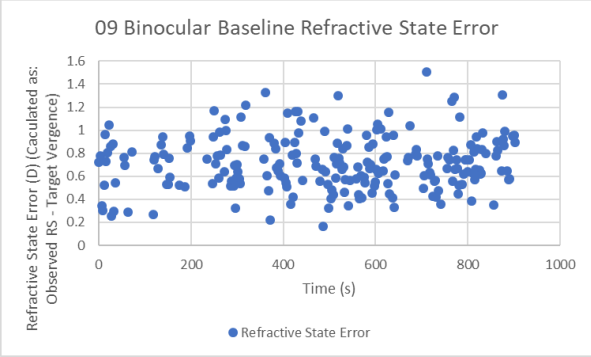


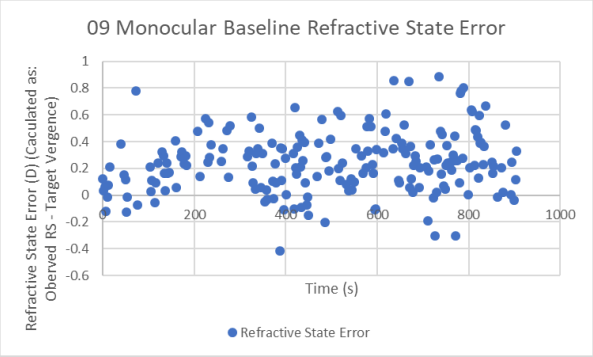


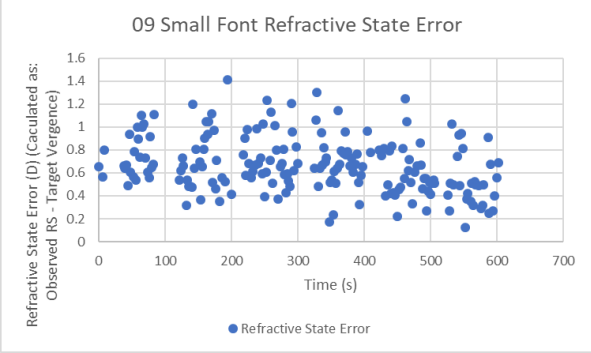
Graph 4.7

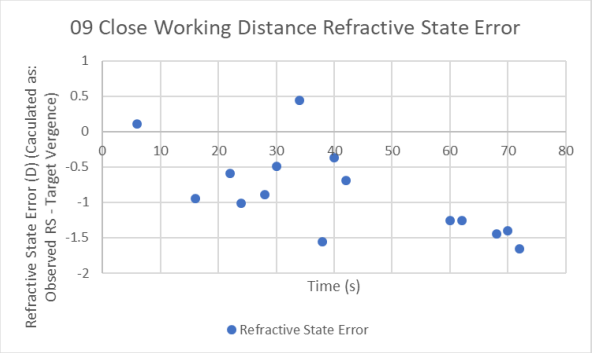
Participant 09 Refractive State Average Error Across Conditions

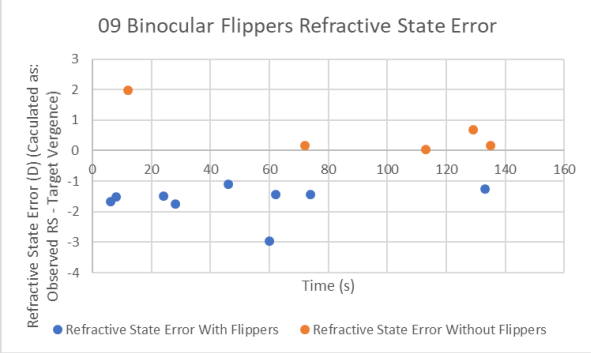


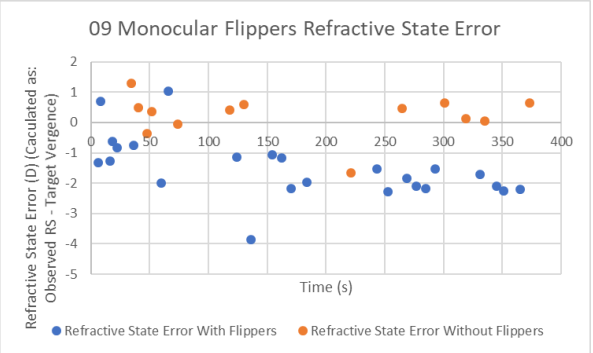






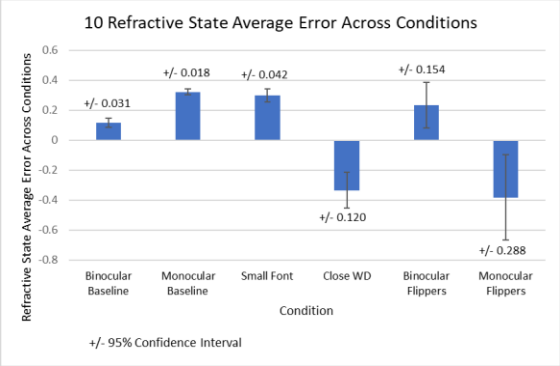


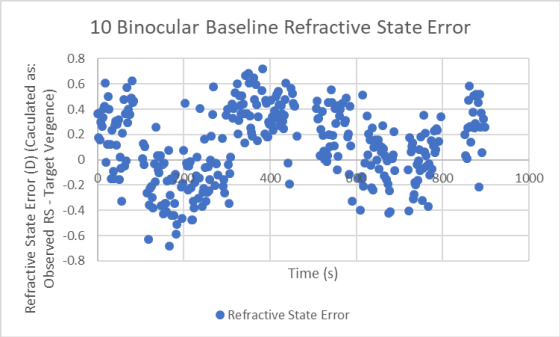


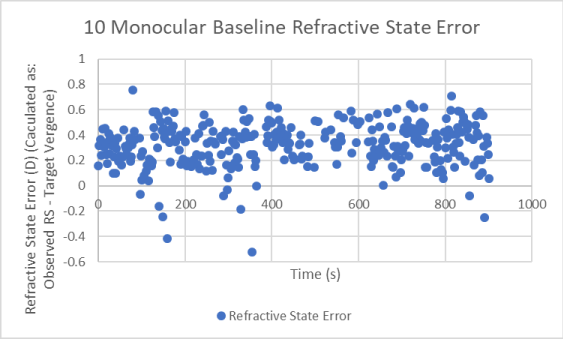


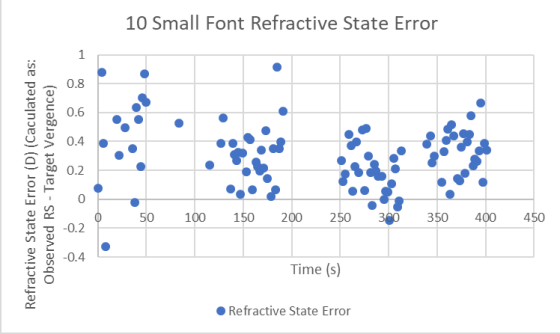
Graph 4.8

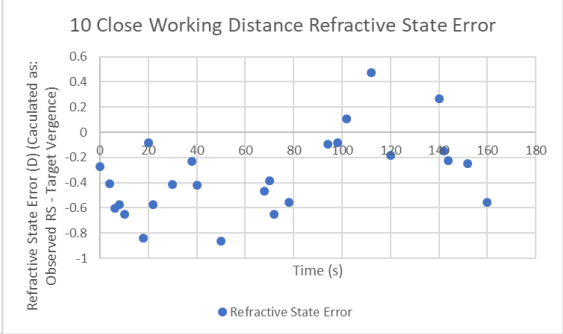
Participant 10 Refractive State Average Error Across Conditions

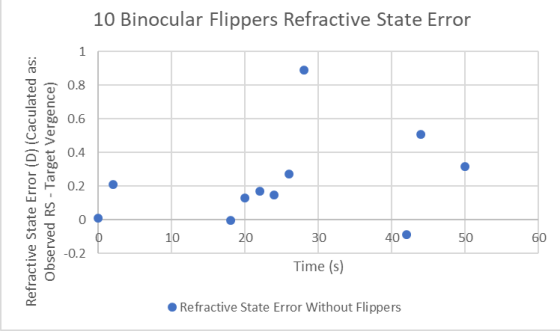


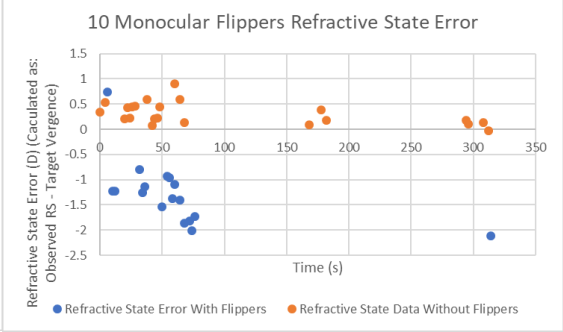










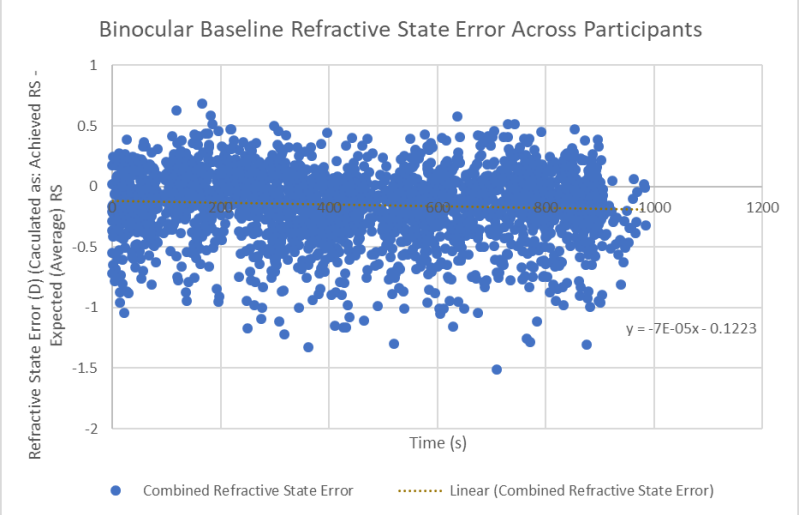


The binocular flippers condition for participant 10 has no data collected without flippers.

To further espouse on the refractive state error over time, the following graphs combine all refractive state error data for all participants onto individual graphs, to provide an average slope.

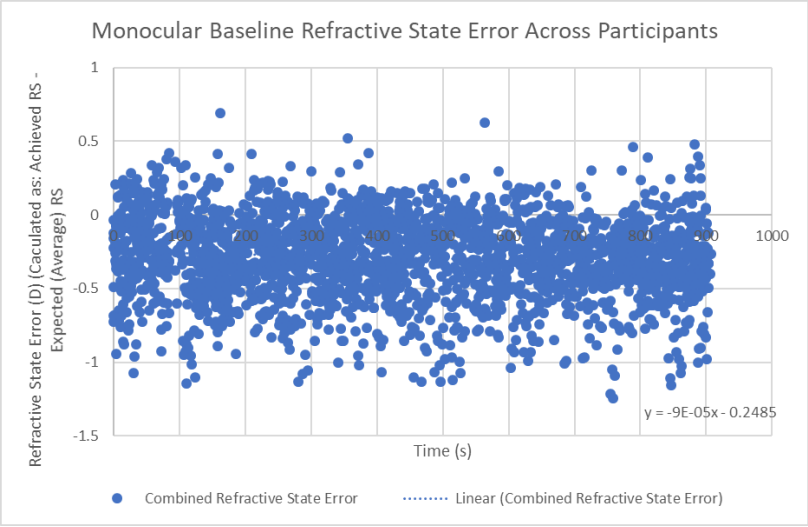
Graph 5.1

Binocular Baseline Refractive State Error Across Participants



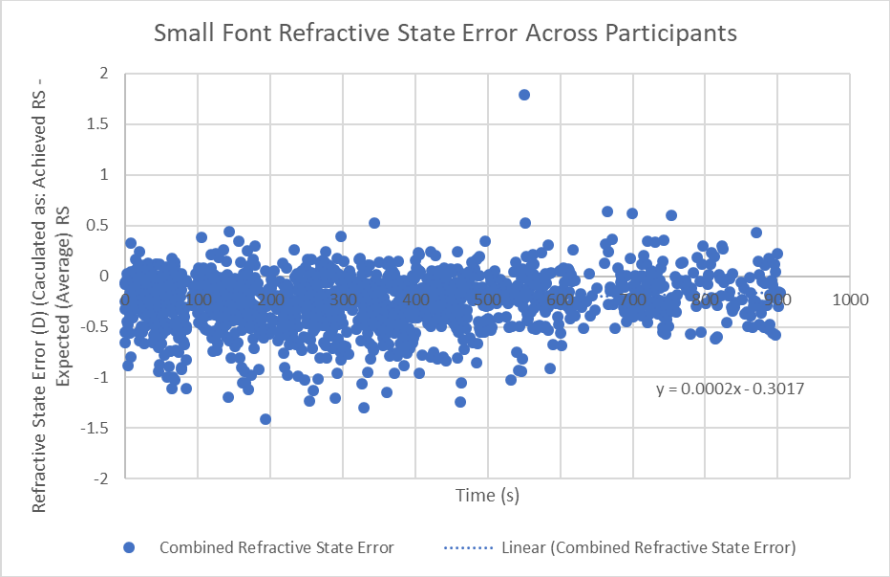
Graph 5.2

Monocular Baseline Refractive State Error Across Participants



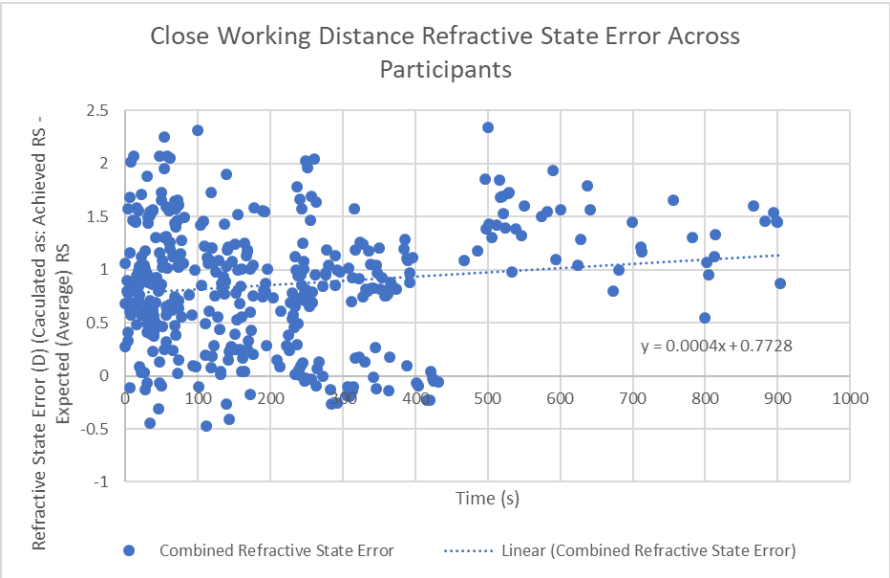
Graph 5.3

Small Font Refractive State Error Across Participants



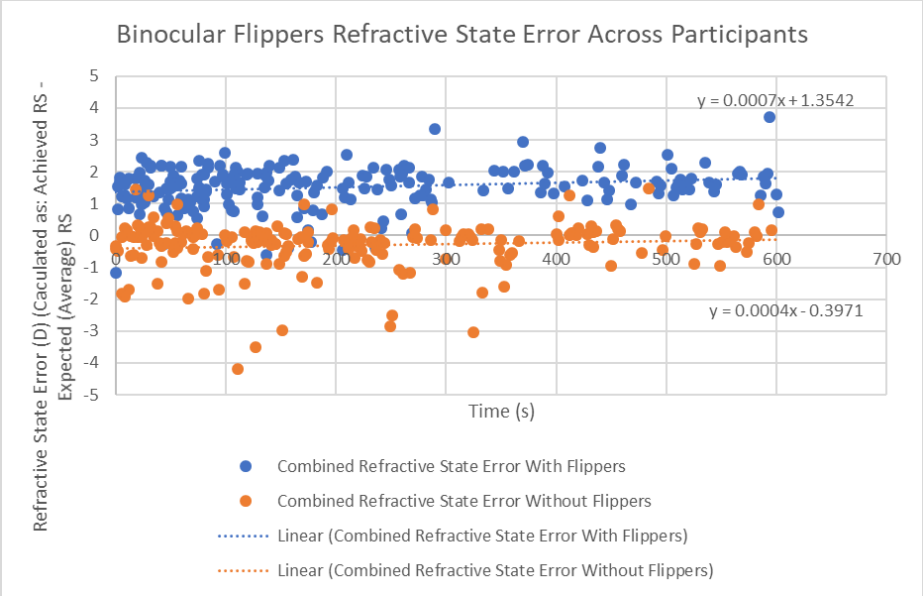
Graph 5.4

Close Working Distance Refractive State Error Across Participants



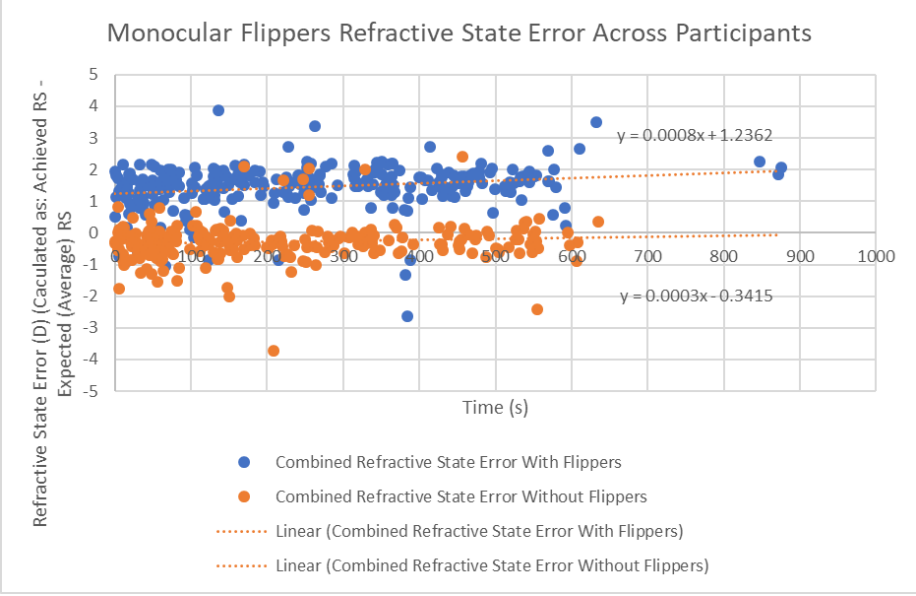
Graph 5.5

Binocular Flippers Refractive State Error Across Participants



Graph 5.6

Monocular Flippers Refractive State Error Across Participants



The slopes found on the preceding graphs may then be analyzed via t-test to determine if the slopes are significantly different from zero. This is presented in Table 9.

Table 9

One-sample Two-tailed T-Test; Ho (that there is no difference between the population mean and zero) is rejected if p<0.05.

Test Condition	**Slope**
Binocular Baseline	-0.00007
Monocular Baseline	-0.00009
Small Font	0.0002
Close Working Distance	0.0004
Binocular Flippers (With Flipper)	0.0007
Binocular Flippers (Without Flipper)	0.0004
Monocular Flippers (With Flipper)	0.0008
Monocular Flippers (Without Flipper)	0.0003
Average	0.00033
Standard Deviation	0.000321
N	8
p	0.0228

As the p-value of 0.0228 is less than 0.05, the null hypothesis is rejected. The slopes are statistically different from zero. This shows that as participants get increasingly fatigued over the duration of the tests, their refractive state errors increase.

To determine if participants who fatigue during the test scenarios have more variance overall, an ANOVA test was performed. The results may be seen in Graph 6.1 and Table 10.

Graph 6.1

Total Variance Across Participants

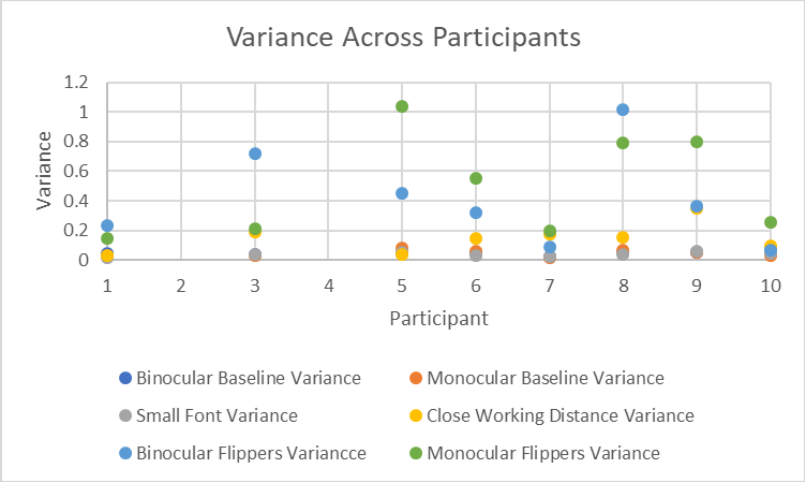


Table 10

ANOVA Results

Participant	Binocular Baseline	Monocular Baseline	Small Font	Close Working Distance	Binocular Flippers	Monocular Flippers
01	0.046118	0.029219	0.016635	0.030535	0.233243	0.142742
03	0.036234	0.03083	0.034282	0.192553	0.719349	0.20969
05	0.045886	0.08229	0.054692	0.036331	0.449612	1.036992
06	0.044086	0.055878	0.027807	0.145786	0.320503	0.549393
07	0.023054	0.017564	0.021873	0.177879	0.085871	0.19411
08	0.05189	0.065567	0.038393	0.15282	1.019165	0.794452
09	0.05374	0.051529	0.057479	0.347914	0.361722	0.798228
10	0.084463	0.028755	0.046469	0.097692	0.067525	0.252999
n	8	8	8	8	8	8
X	0.048	0.045	0.037	0.148	0.407	0.497
s	0.018	0.022	0.015	0.101	0.323	0.345
$\mathbf{X}_{average}$	0.197					

Source	df	SS	MS	F	P-value
Treatments	5	1.66	0.332	8.4822	0
Error	42	1.644	0.039		
Total	47	3.304			

These ANOVA results show that $p<0.05$. Therefore, the null hypothesis that there is no difference between variances across conditions is rejected. This indicates that as participants become fatigued, they have an increase in the amount of refractive state error variance.

Another analysis of variance allows determination of if variance increases over the course of a test scenario. This was performed by comparing the first 10 variance measures during each test scenario, with the last 10 variance measures. The results may be seen in Graph 6.6 and Table 11.

Graph 6.2

Change in Variance Across Participants

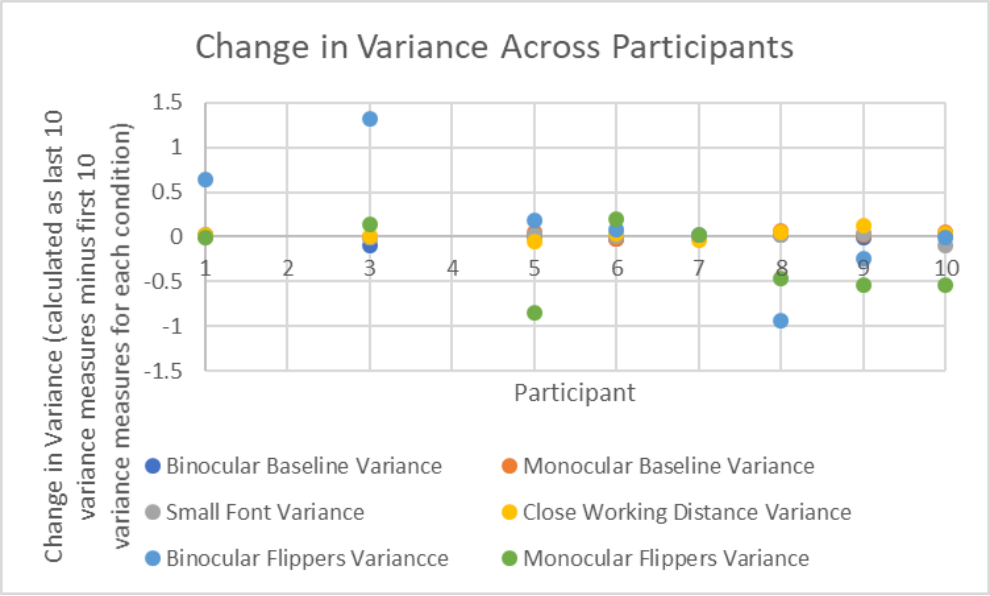


Table 11

ANOVA Results

Participant	**Binocular Baseline**	**Monocular Baseline**	**Small Font**	**Close Working Distance**	**Binocular Flippers**	**Monocular Flippers**
01	0.046118	0.029219	0.016635	0.030535	0.233243	0.142742
03	0.036234	0.03083	0.034282	0.192553	0.719349	0.20969
05	0.045886	0.08229	0.054692	0.036331	0.449612	1.036992
06	0.044086	0.055878	0.027807	0.145786	0.320503	0.549393
07	0.023054	0.017564	0.021873	0.177879	0.085871	0.19411
08	0.05189	0.065567	0.038393	0.15282	1.019165	0.794452
09	0.05374	0.051529	0.057479	0.347914	0.361722	0.798228
10	0.084463	0.028755	0.046469	0.097692	0.067525	0.252999
n	8	8	8	8	8	8
X	0.048	0.045	0.037	0.148	0.407	0.497
s	0.018	0.022	0.015	0.101	0.323	0.345
$\mathbf{X}_{ave}$	0.197					

Source	**df**	**SS**	**MS**	**F**	**P-value**
Treatments	5	0.657	0.131	1.3495	0.2627
Error	42	4.09			
Total	47	4.747			

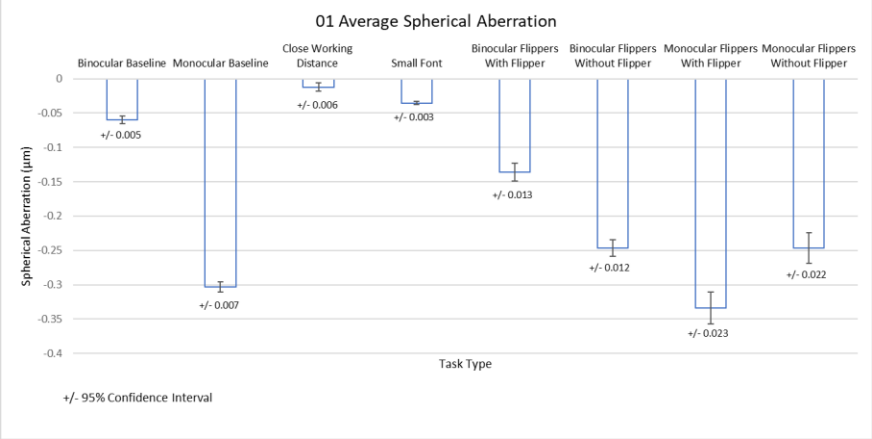
These ANOVA results show that $p>0.05$. Therefore, the null hypothesis that here is there is no difference between change in variances across conditions is not rejected. This indicates that the variance does not steadily increase over the course of a test condition as the participant becomes fatigued.

These refractive state results, beginning with graph group 3 on page 49, are further explored in the discussion section.

The next measure the COAS aberrometer performed was to measure the spherical aberration of the participants' eye. These findings are separated into graph groups 7, 8 and 9 on the following pages.

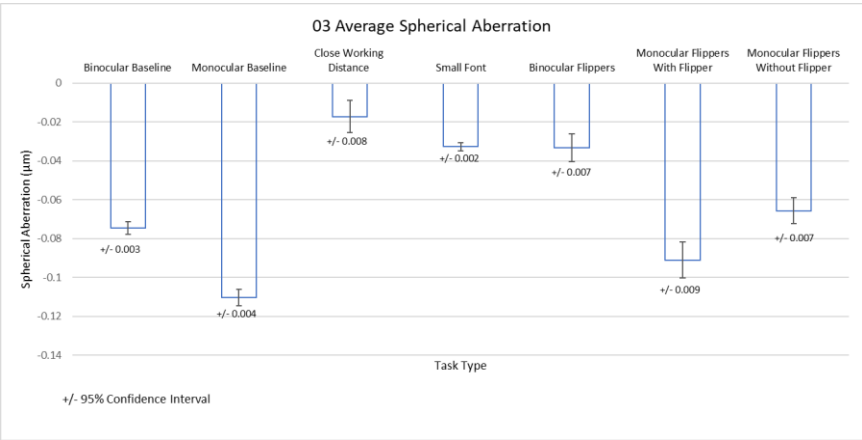
Graph 7.1

Participant 01 Average Spherical Aberration Graph



Graph 7.2

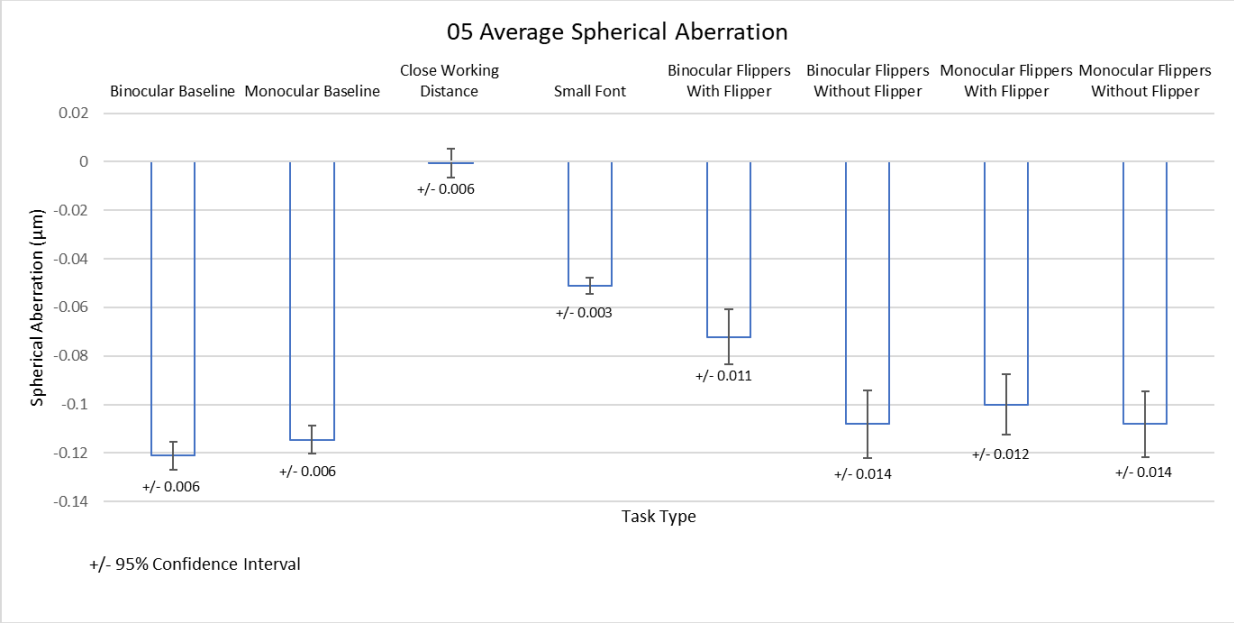
Participant 03 Average Spherical Aberration Graph



As stated previously, the location of the flippers (in or out) for participant 3 is data missing at random.

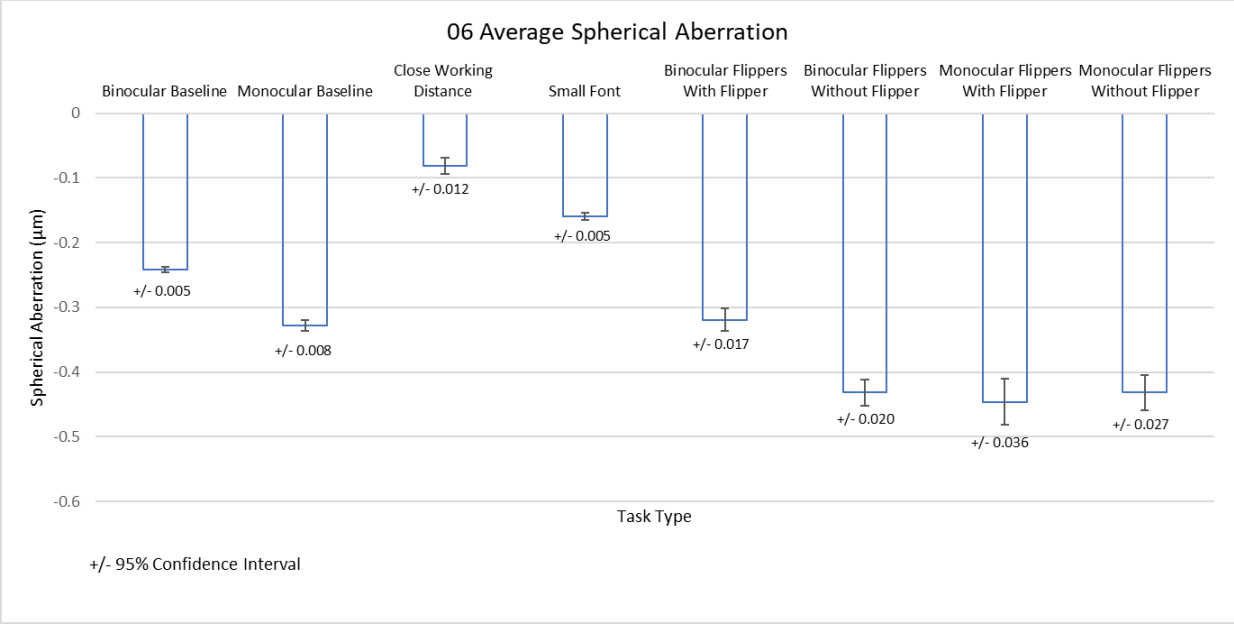
Graph 7.3

Participant 05 Average Spherical Aberration Graph



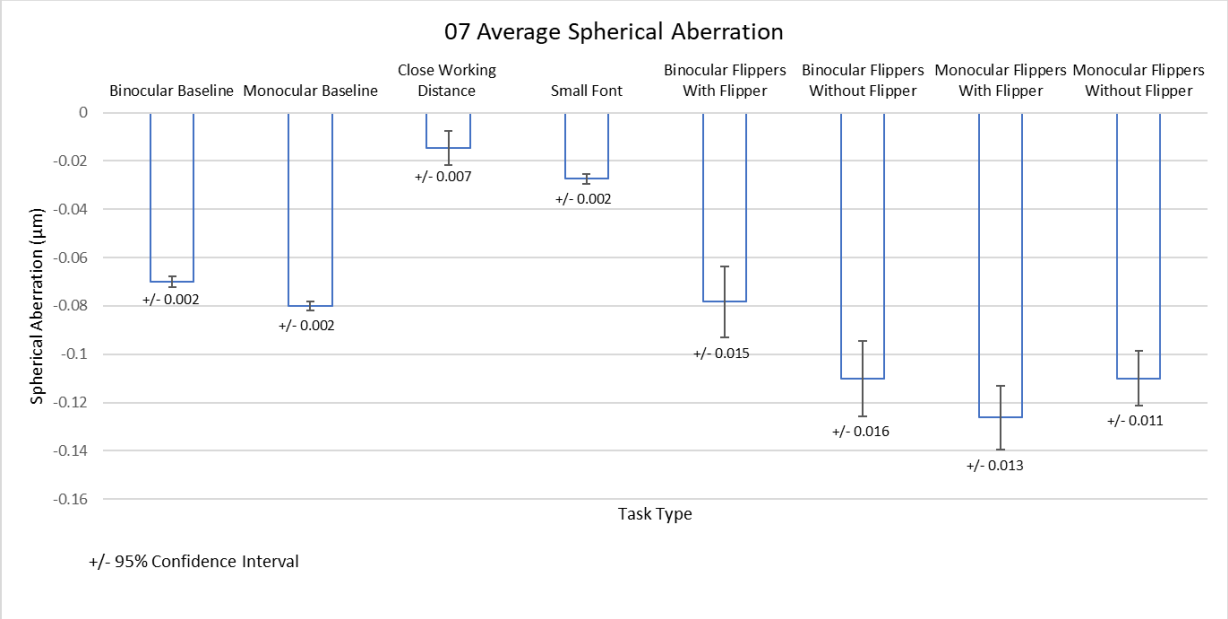
Graph 7.4

Participant 06 Average Spherical Aberration Graph



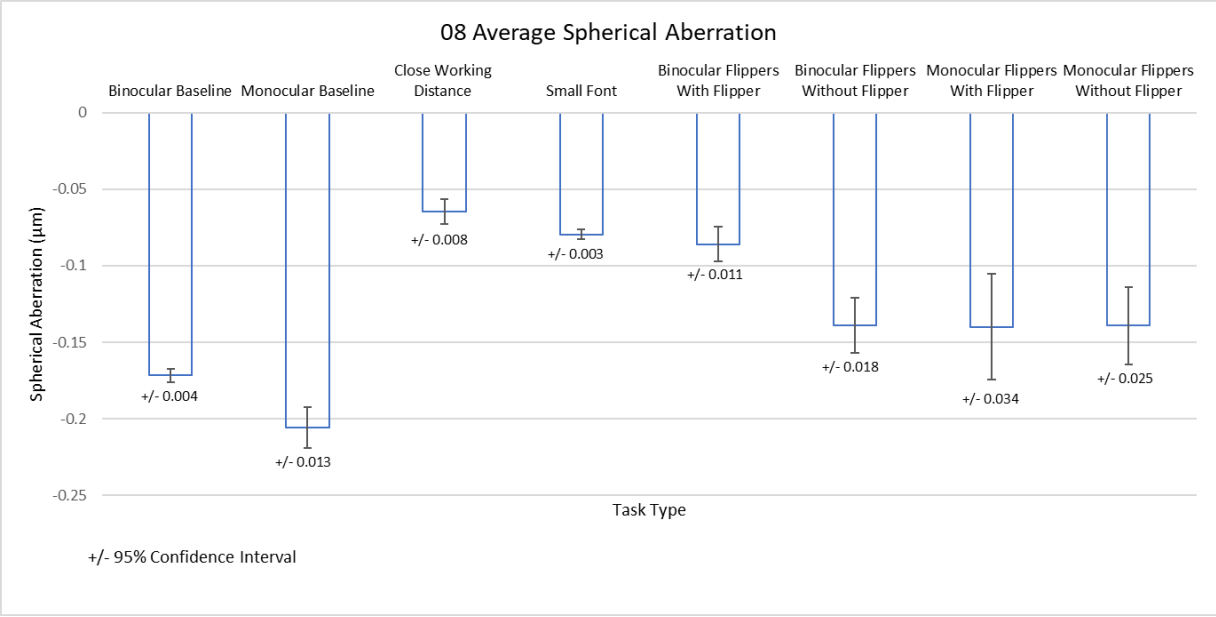
Graph 7.5

Participant 07 Average Spherical Aberration Graph



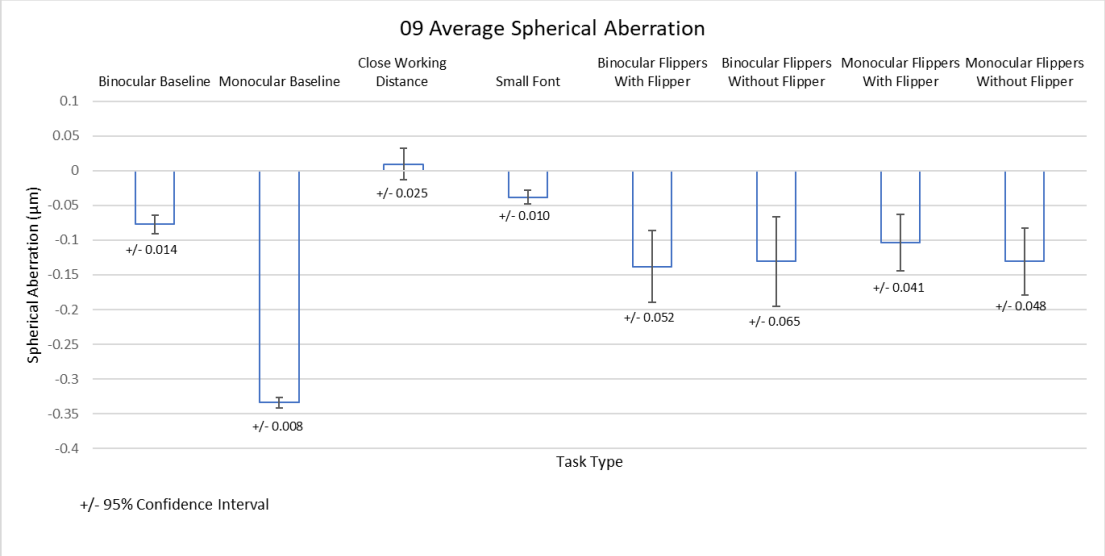
Graph 7.6

Participant 08 Average Spherical Aberration Graph



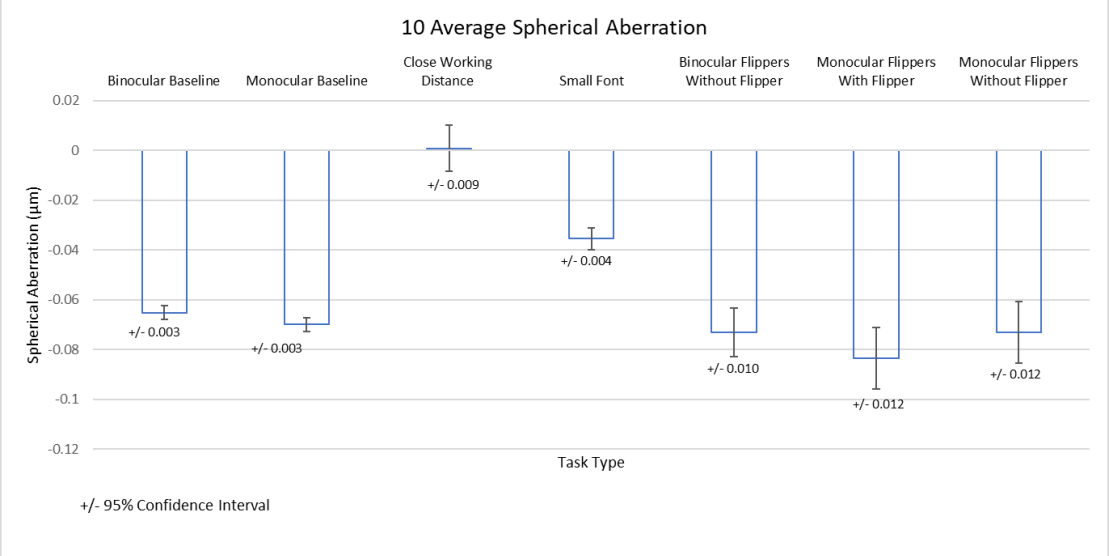
Graph 7.7

Participant 09 Average Spherical Aberration Graph



Graph 7.8

Participant 10 Average Spherical Aberration Graph



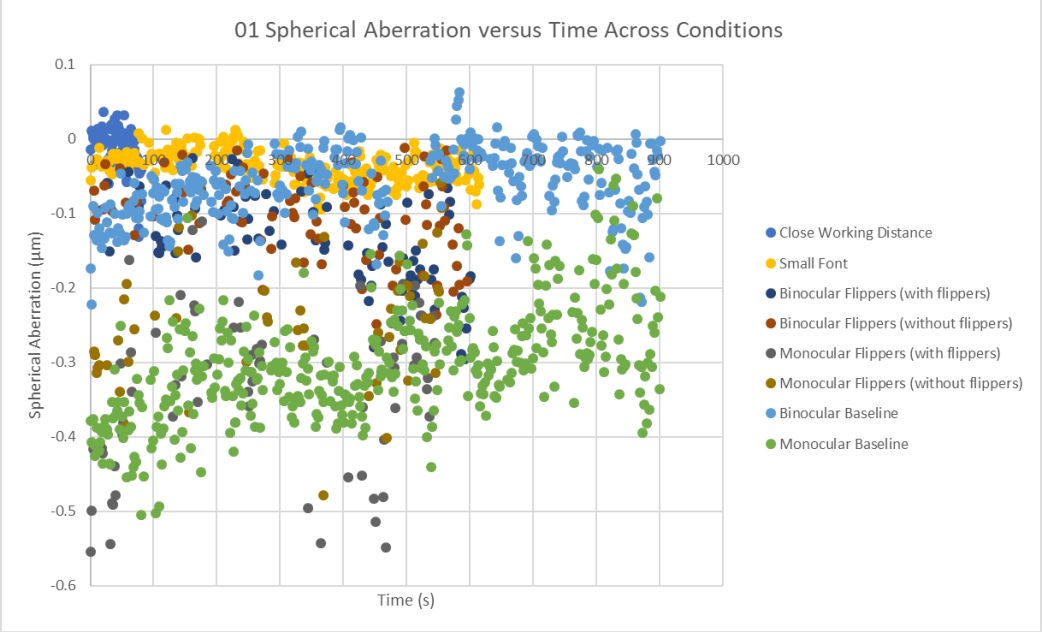
As stated previously, no data was collected for the binocular flippers with flippers for participant 10.

The preceding graphs show that in all testing scenarios and across all participants (except for two outliers, participants 09 and 10, in the close working distance condition only), the spherical aberration was found to be negative. This is a surprising finding, which is analyzed in depth in the discussion section.

The following graphs illustrate how spherical aberration varied over time for each participant.

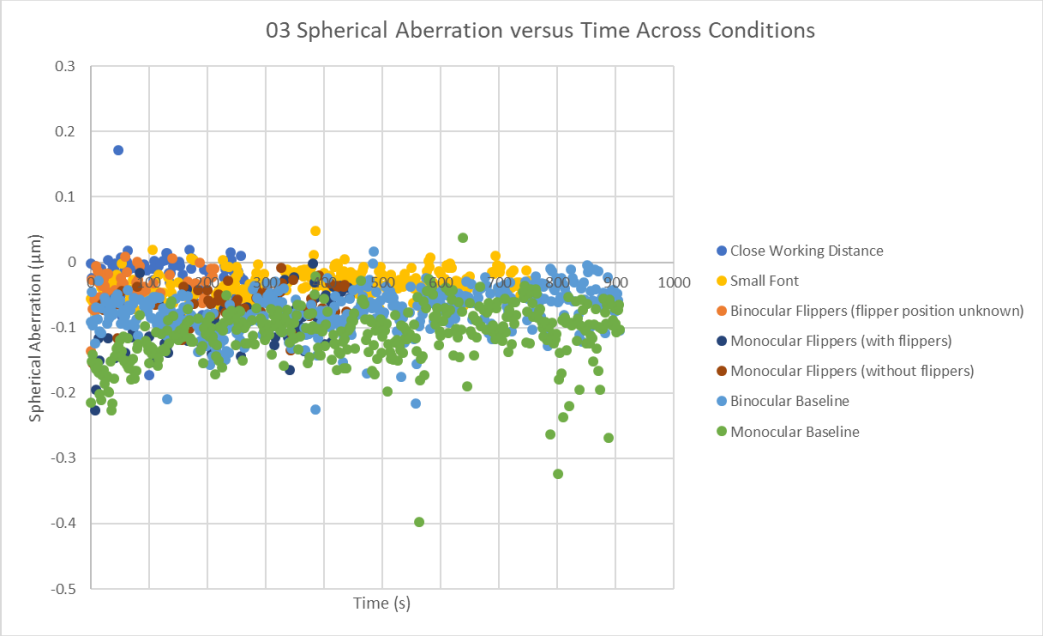
Graph 8.1

Participant 01 Spherical Aberration versus Time



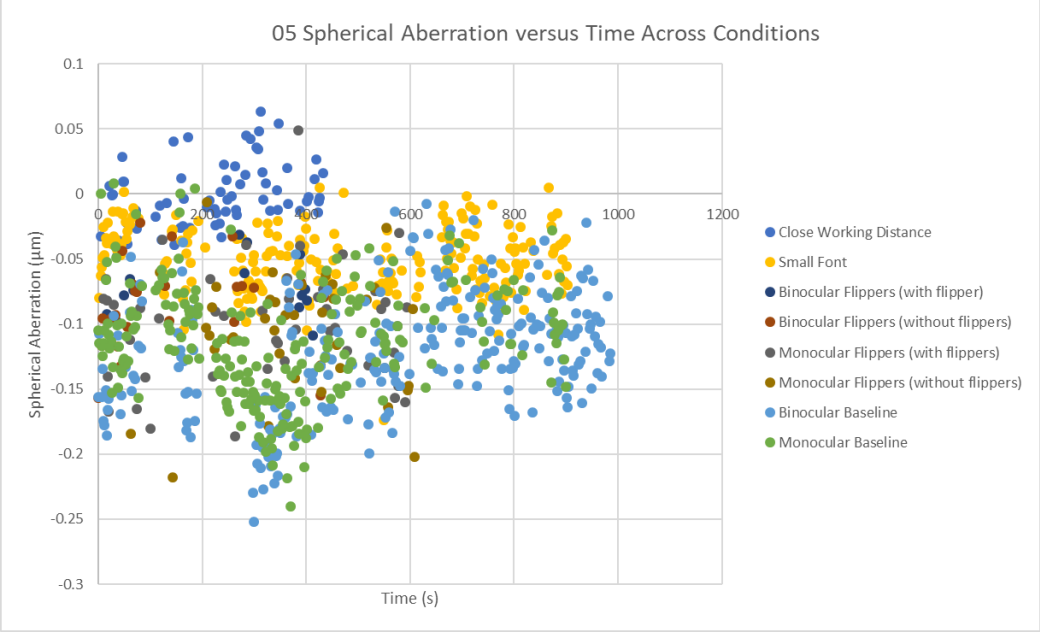
Graph 8.2

Participant 03 Spherical Aberration versus Time



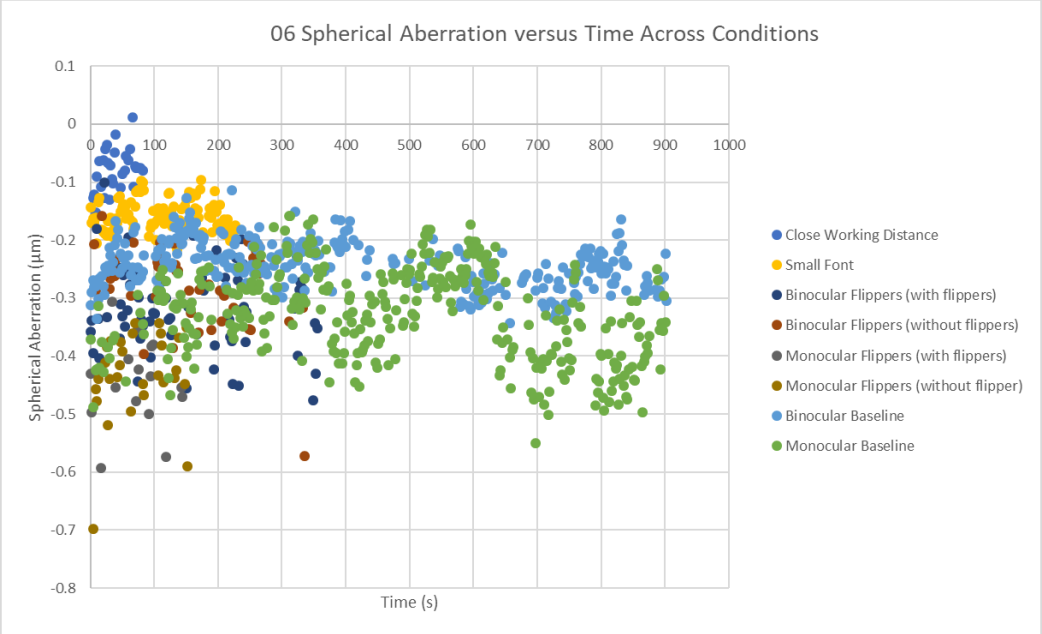
Graph 8.3

Participant 05 Spherical Aberration versus Time



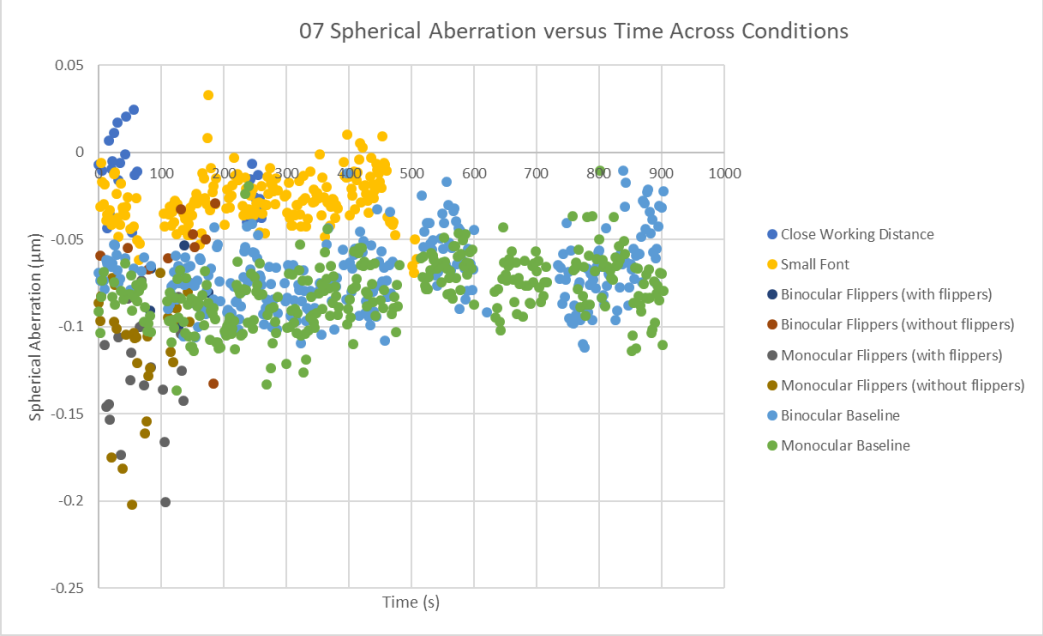
Graph 8.4

Participant 06 Spherical Aberration versus Time



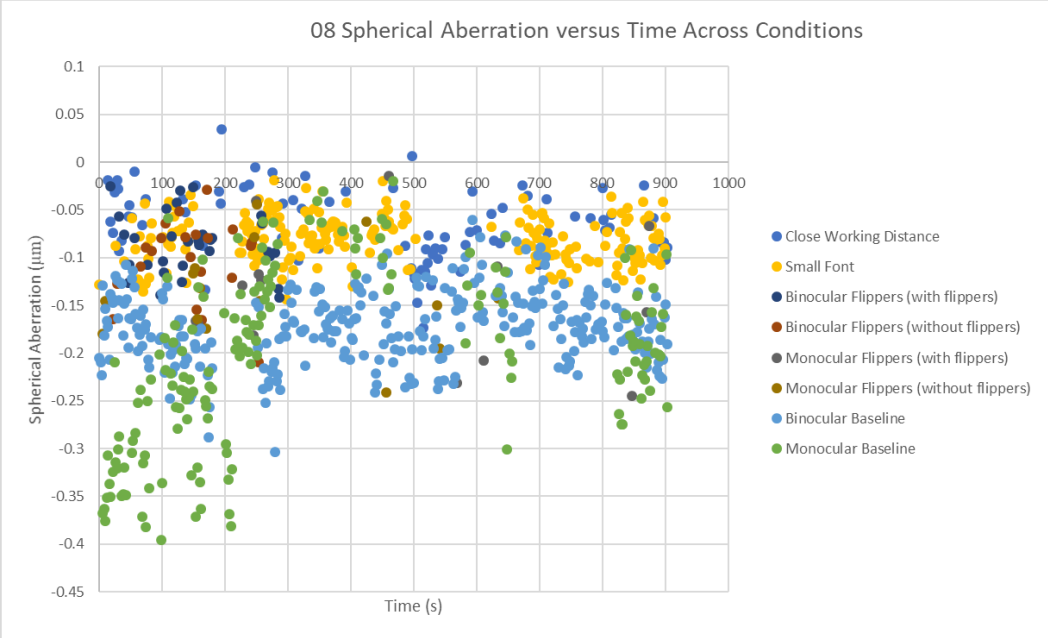
Graph 8.5

Participant 07 Spherical Aberration versus Time



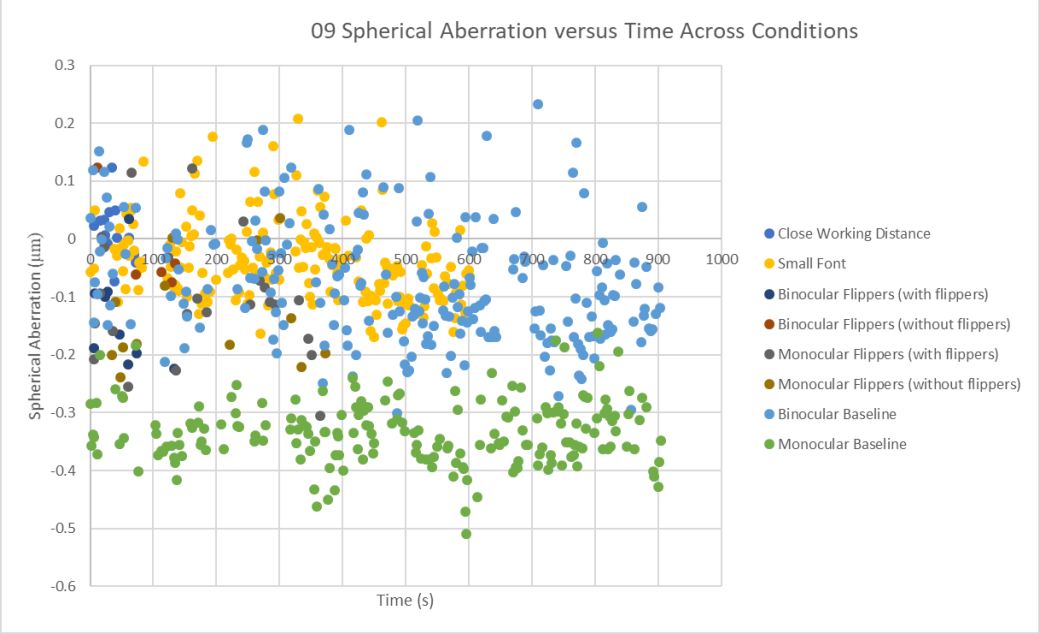
Graph 8.6

Participant 08 Spherical Aberration versus Time



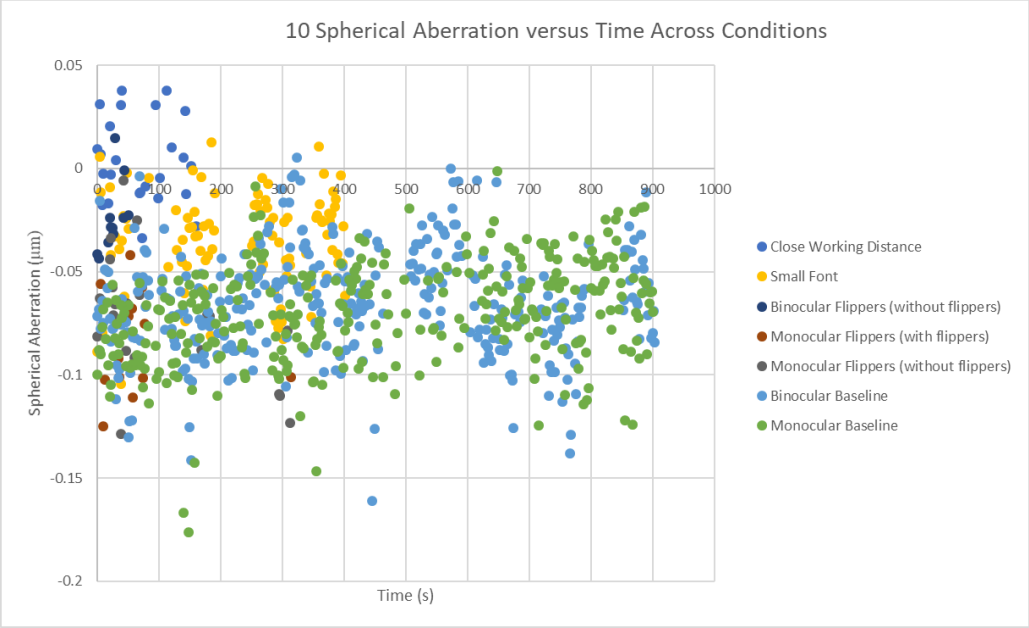
Graph 8.7

Participant 09 Spherical Aberration versus Time



Graph 8.8

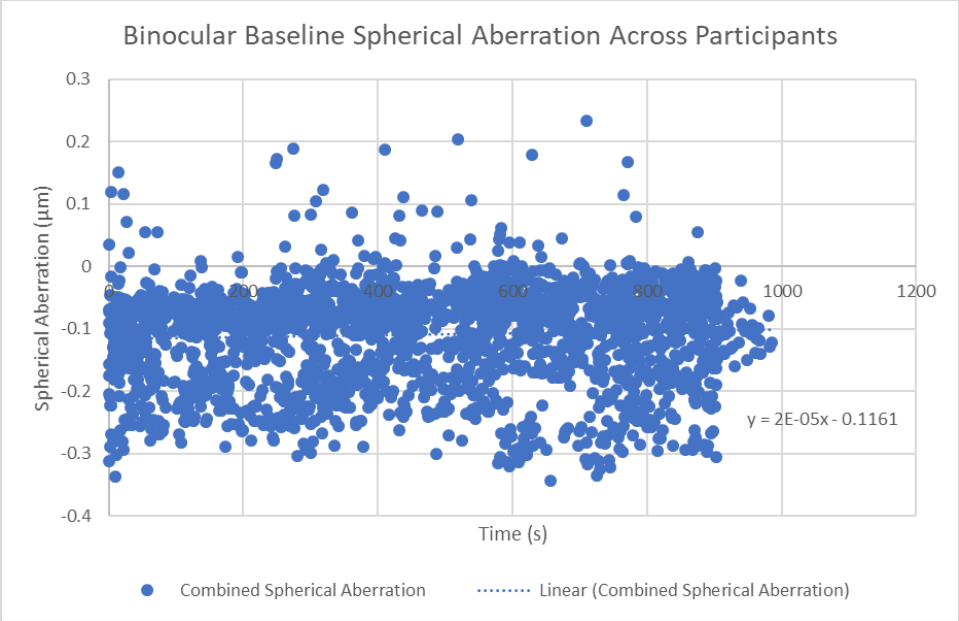
Participant 10 Spherical Aberration versus Time



The spherical aberration over time graphs show that the spherical aberration was generally stable (horizontal) for each participant in each condition. This is proven mathematically in table 12, below, after graphs 9.1 through 9.6 illustrate the spherical aberration across participants for each condition.

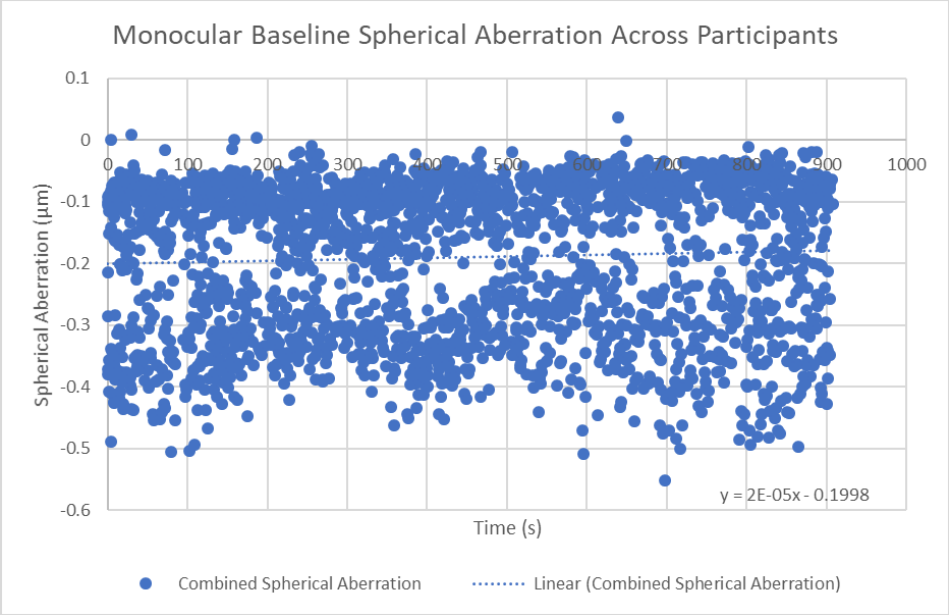
Graph 9.1

Binocular Baseline Spherical Aberration Across Participants



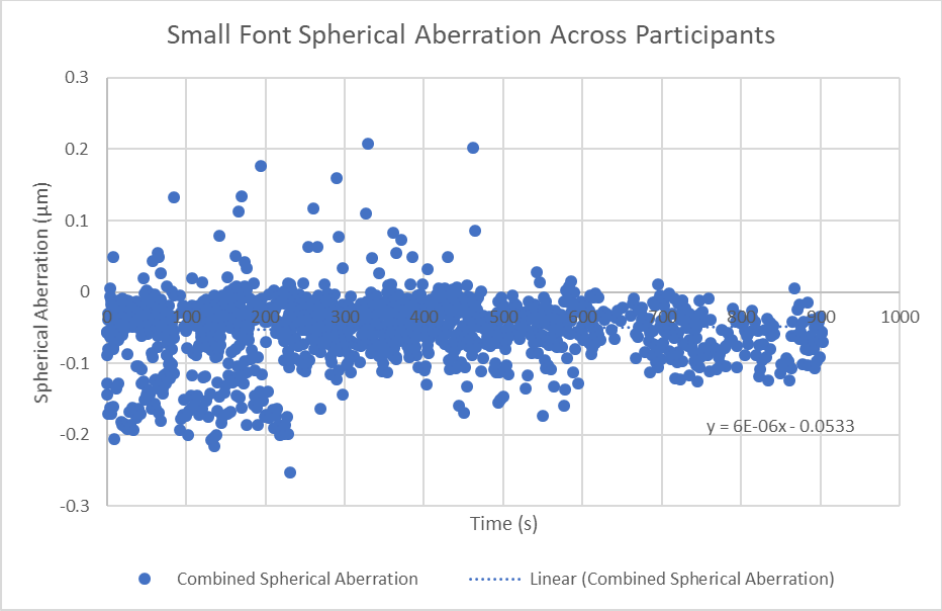
Graph 9.2

Monocular Baseline Spherical Aberration Across Participants



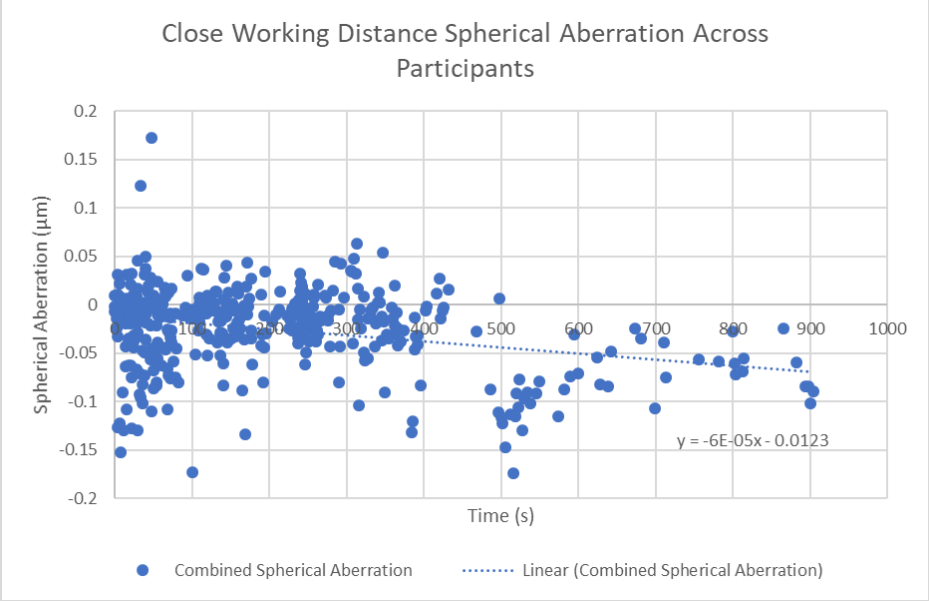
Graph 9.3

Small Font Spherical Aberration Across Participants



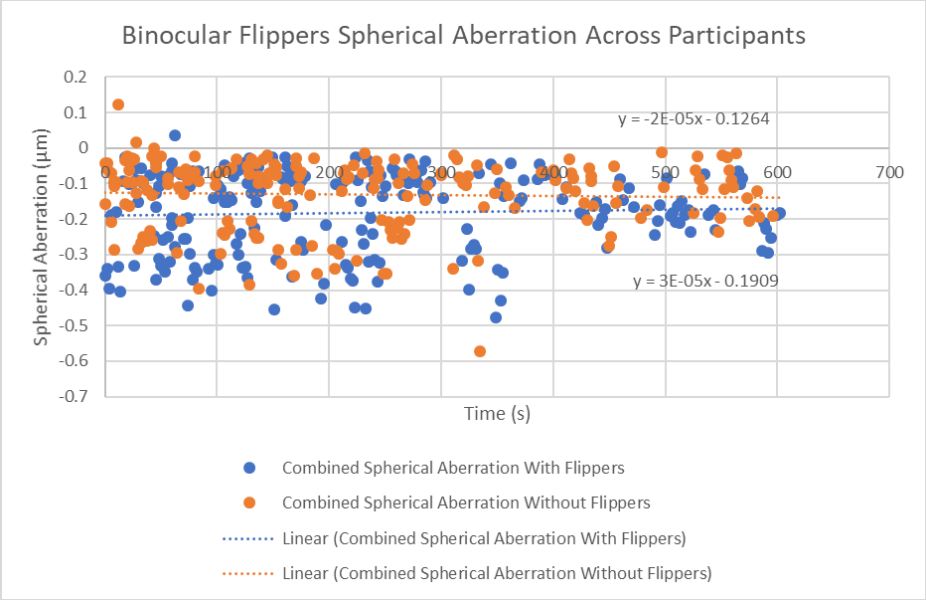
Graph 9.4

Close Working Distance Spherical Aberration Across Participants



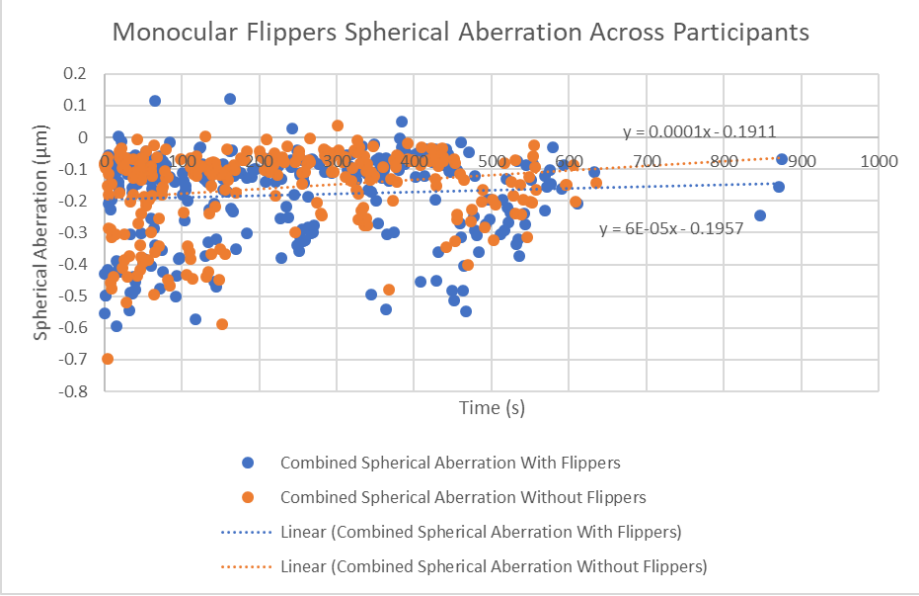
Graph 9.5

Binocular Flippers Spherical Aberration Across Participants



Graph 9.6

Monocular Flippers Spherical Aberration Across Participants



The slopes found on the preceding graphs may then be analyzed via t-test to determine if the slopes are significantly different from zero. This is presented in Table 12.

Table 12

One-sample Two-tailed T-Test; Ho (that there is no difference between the population mean and zero) is rejected if p<0.05.

Test Condition	**Slope**
Binocular Baseline	0.00002
Monocular Baseline	0.00002
Small Font	0.000006
Close Working Distance	-0.00006
Binocular Flippers (With Flipper)	0.00003
Binocular Flippers (Without Flipper)	-0.00002
Monocular Flippers (With Flipper)	0.00006
Monocular Flippers (Without Flipper)	0.0001
Average	1.95E-05
Standard Deviation	4.82E-05
N	8
p	0.2905

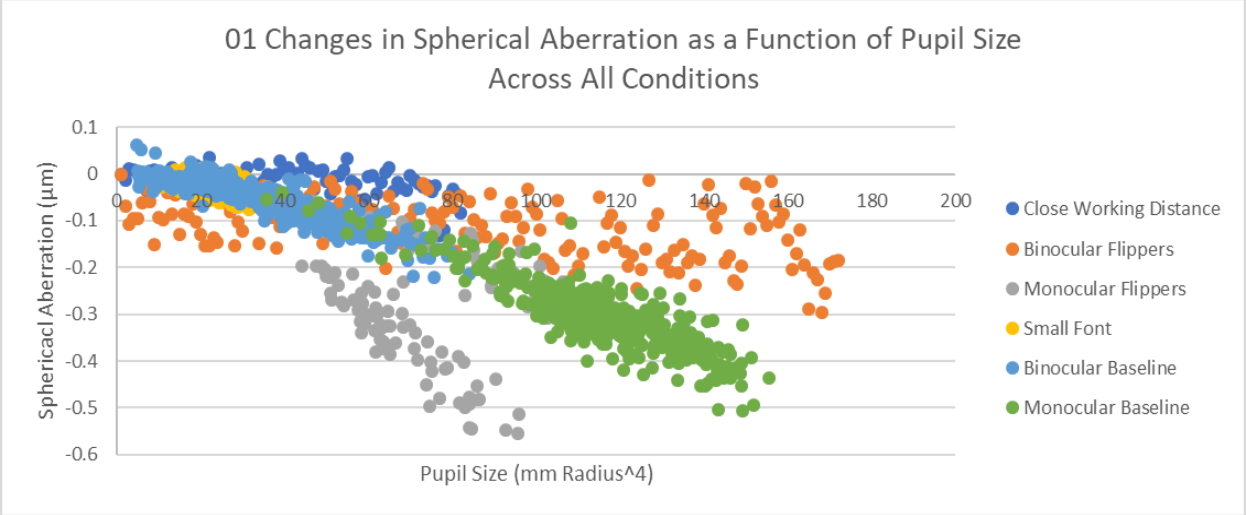
As the p-value of 0.2905 is greater than 0.05, the null hypothesis is not rejected. The slopes are not statistically different from zero. This shows that as participants get increasingly fatigued over the duration of the tests, their spherical aberrations remain stable.

While pupil size can be eliminated as a variable in some case (e.g. the minRMS measure of refractive state varies with pupil size, but measures of central refractive state do not), spherical

aberration is always intrinsically linked to pupil size. The next graphs (10.1 through 10.8) represent the relationship between spherical aberration and pupil size. Pupil size will be further explored in graphs 11.1 through 11.8.

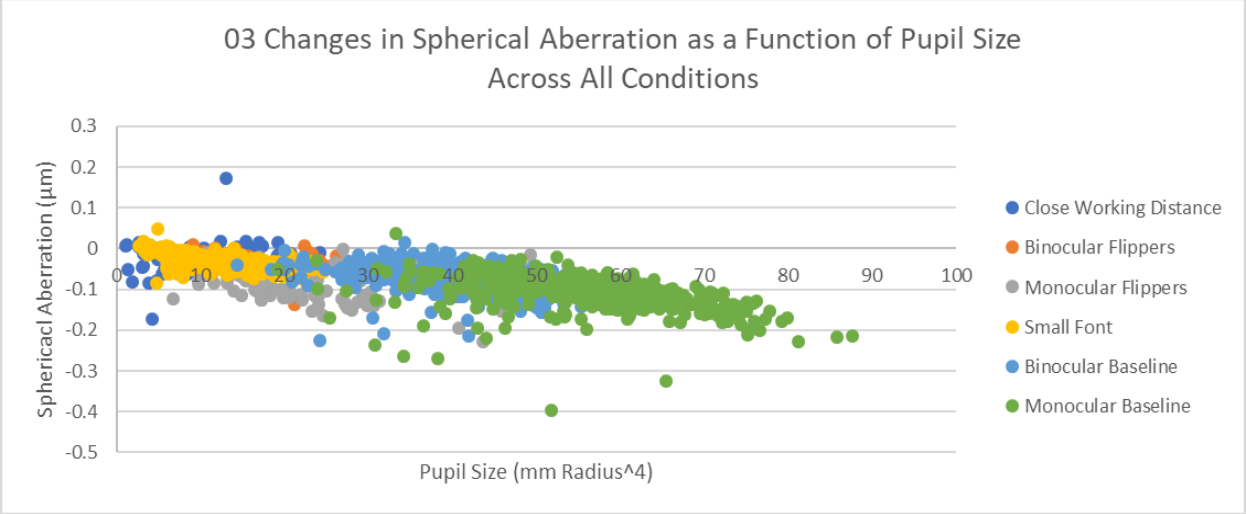
Graph 10.1

Participant 01 Spherical Aberration versus Pupil Size



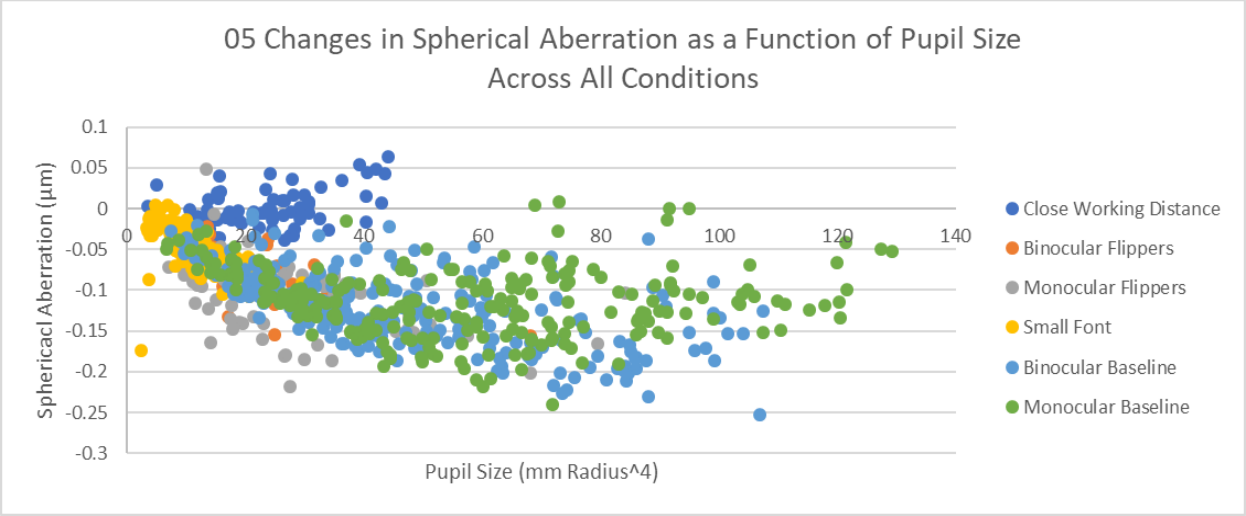
Graph 10.2

Participant 03 Spherical Aberration versus Pupil Size



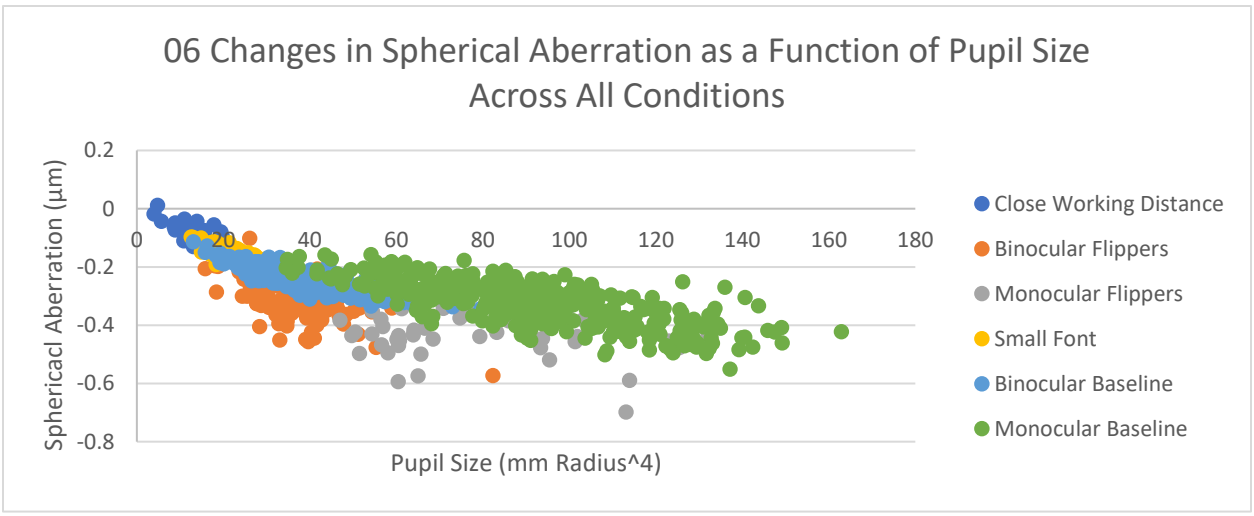
Graph 10.3

Participant 05 Spherical Aberration versus Pupil Size



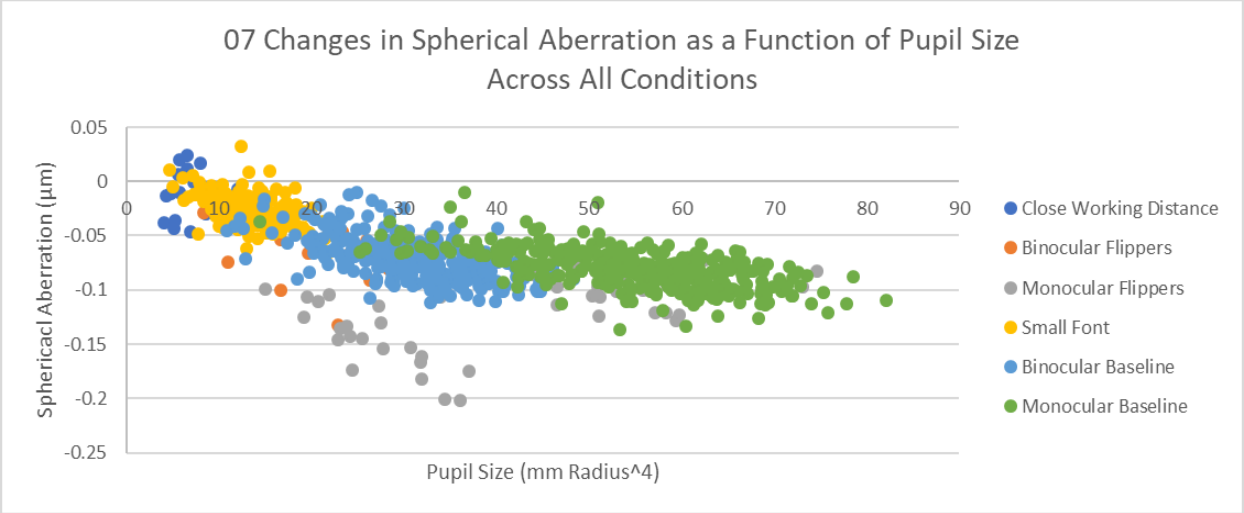
Graph 10.4

Participant 06 Spherical Aberration versus Pupil Size



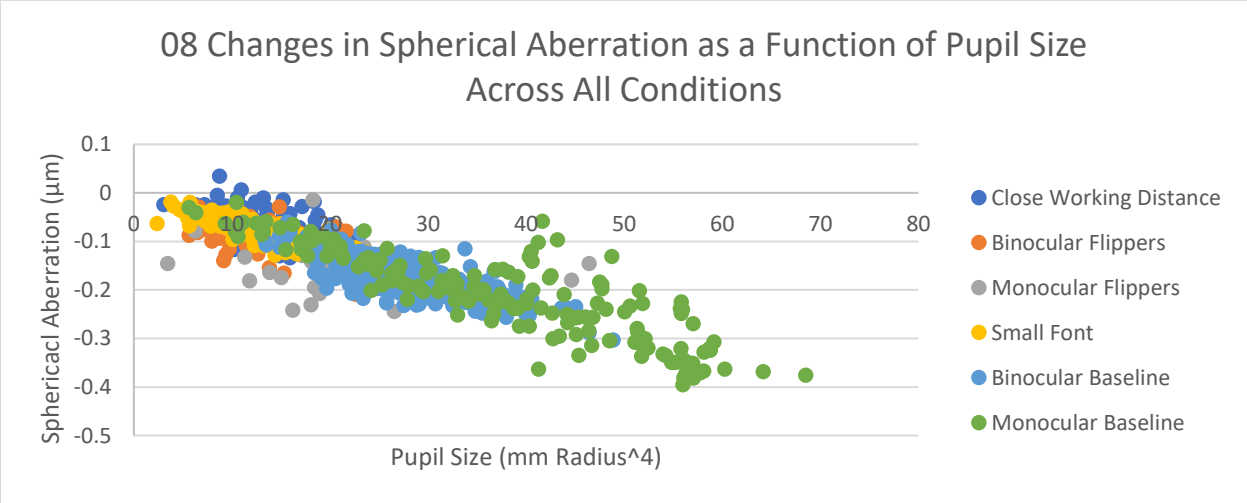
Graph 10.5

Participant 07 Spherical Aberration versus Pupil Size



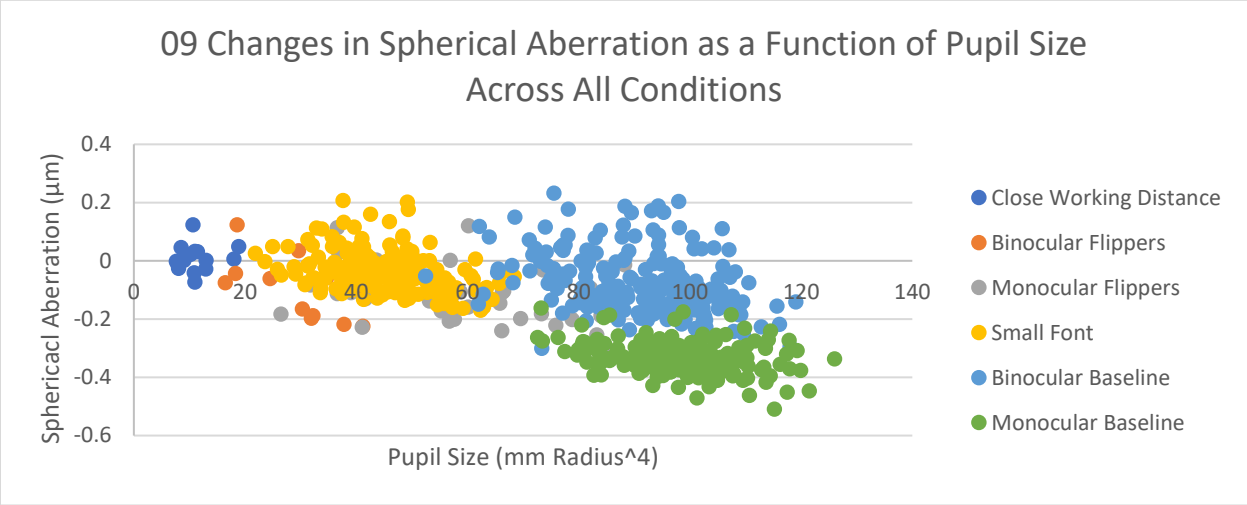
Graph 10.6

Participant 08 Spherical Aberration versus Pupil Size



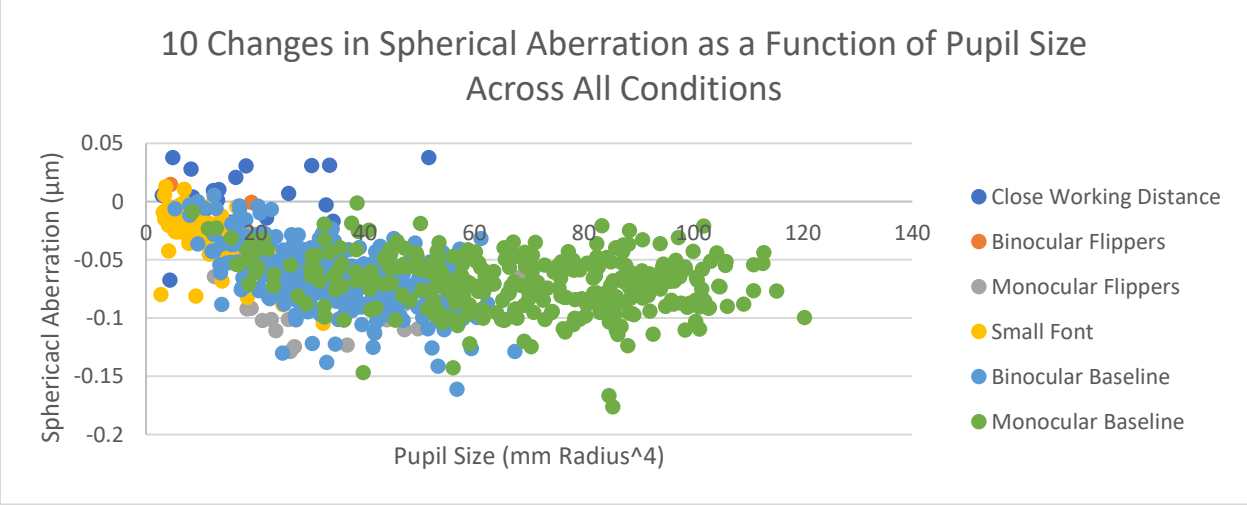
Graph 10.7

Participant 09 Spherical Aberration versus Pupil Size



Graph 10.8

Participant 10 Spherical Aberration versus Pupil Size

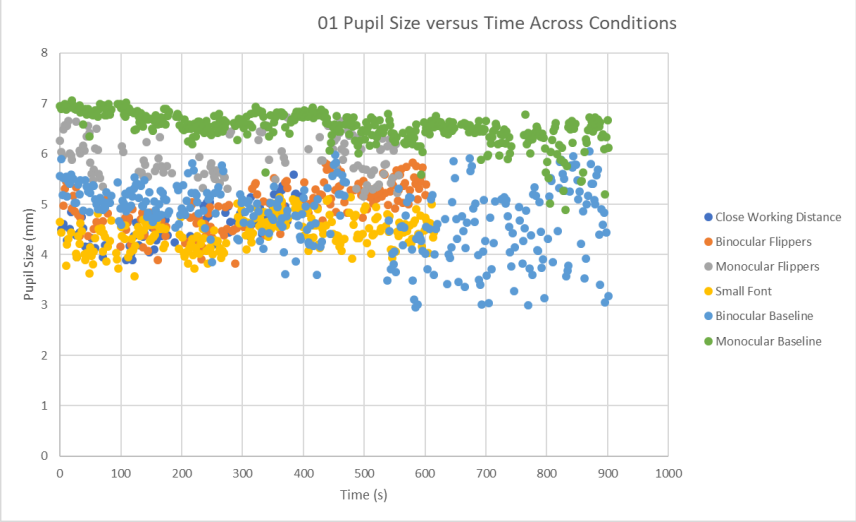


The preceding graphs clearly indicate that as pupil size enlarges, the amount of spherical aberration also increases. The correlation between spherical aberration and pupil size is further explored in the discussion section.

Pupil size individually may also be analyzed to determine how it was affected over the duration of the study. Graphs 11.1 through 11.8, graphs 12.1 through 12.6, and table 13 present this data.

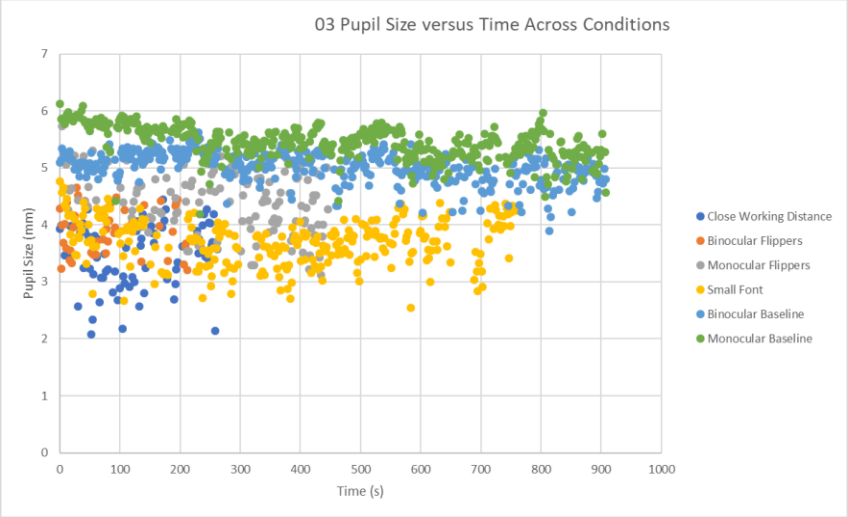
Graph 11.1

Participant 01 Pupil Size versus Time



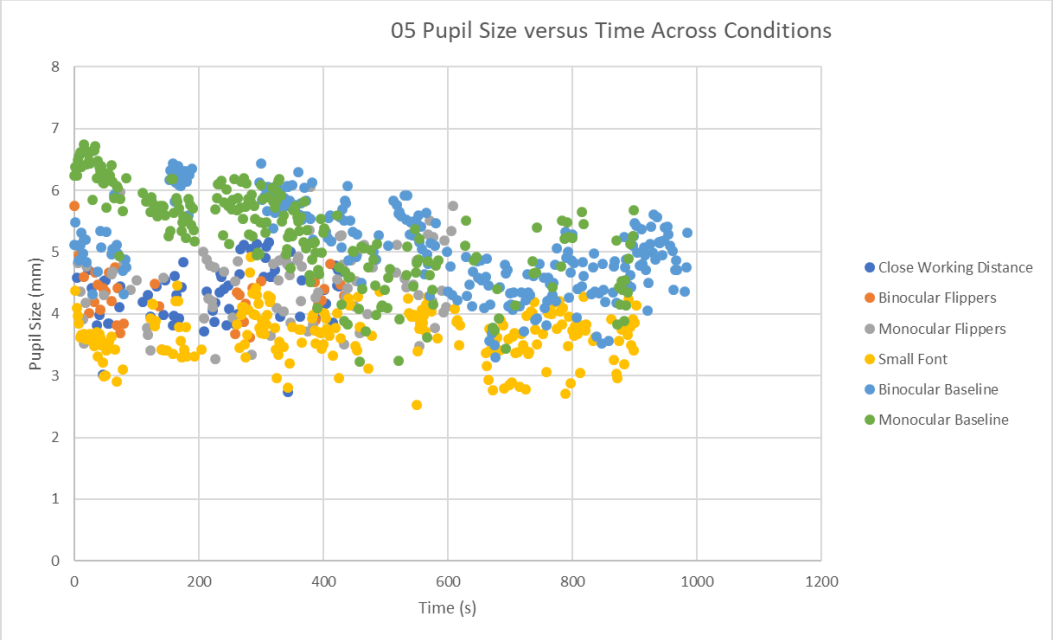
Graph 11.2

Participant 03 Pupil Size versus Time



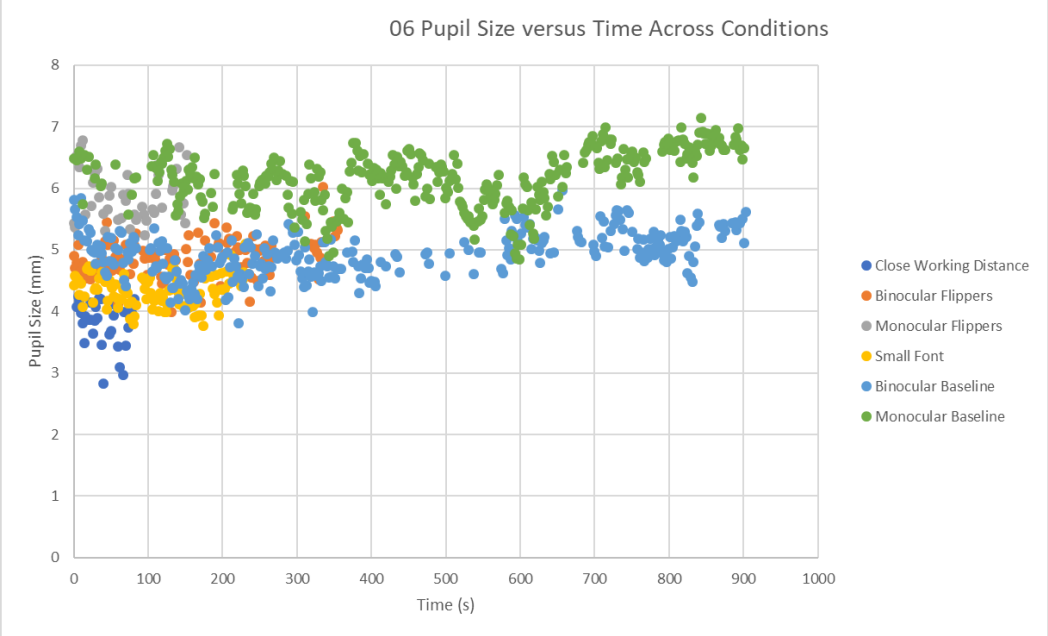
Graph 11.3

Participant 05 Pupil Size versus Time



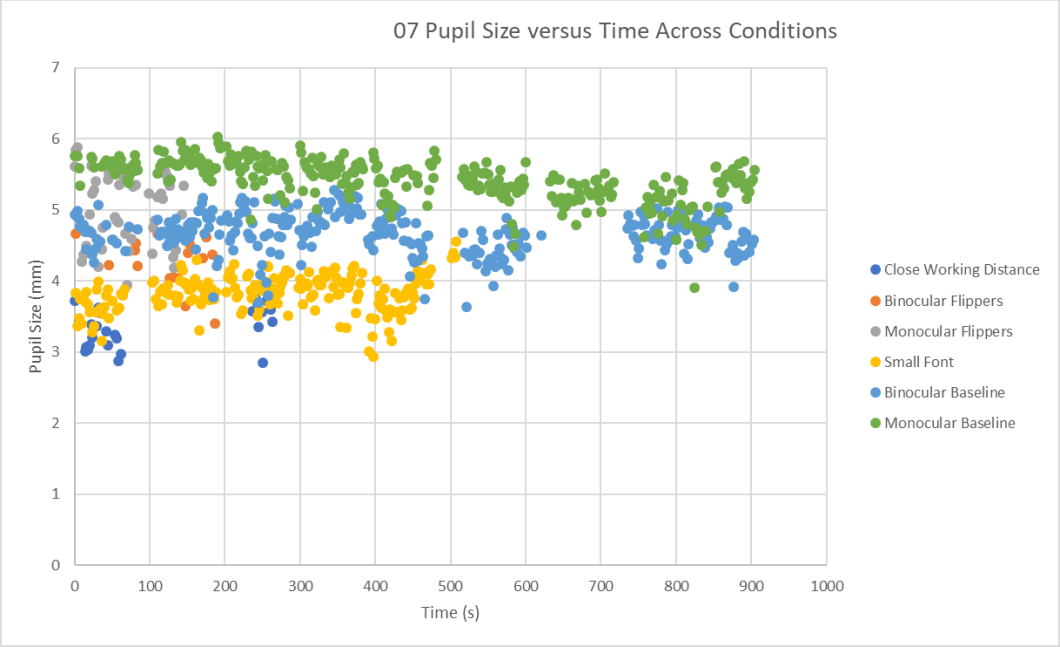
Graph 11.4

Participant 06 Pupil Size versus Time



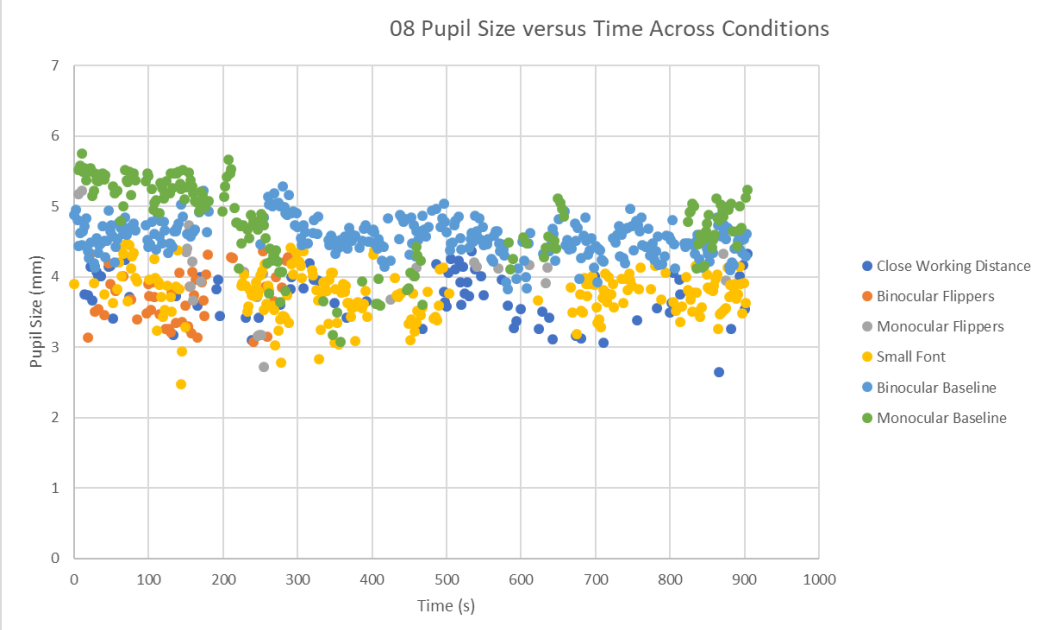
Graph 11.5

Participant 07 Pupil Size versus Time



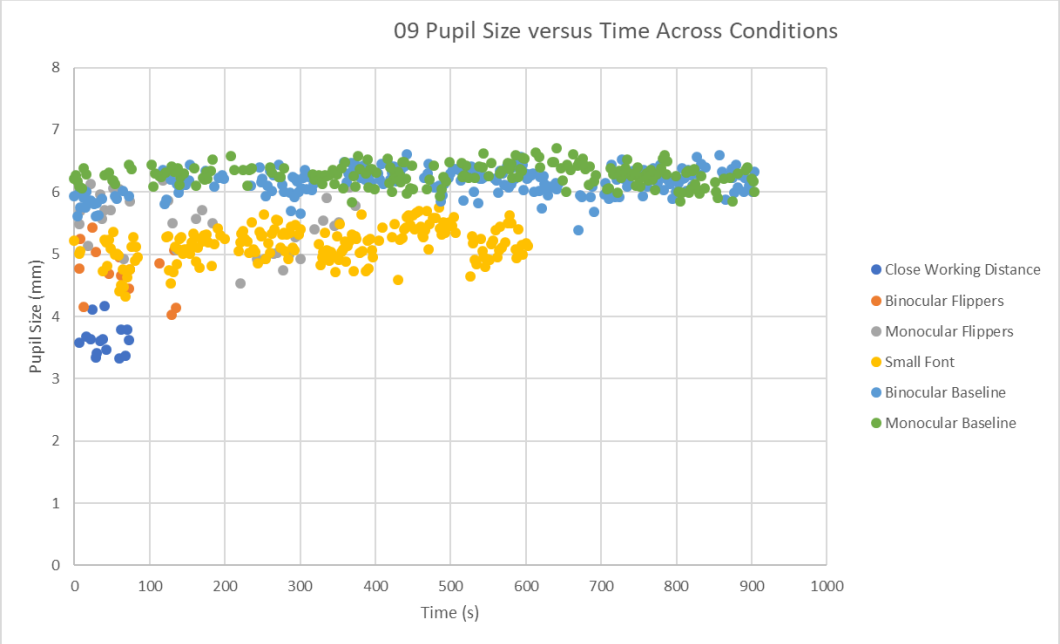
Graph 11.6

Participant 08 Pupil Size versus Time



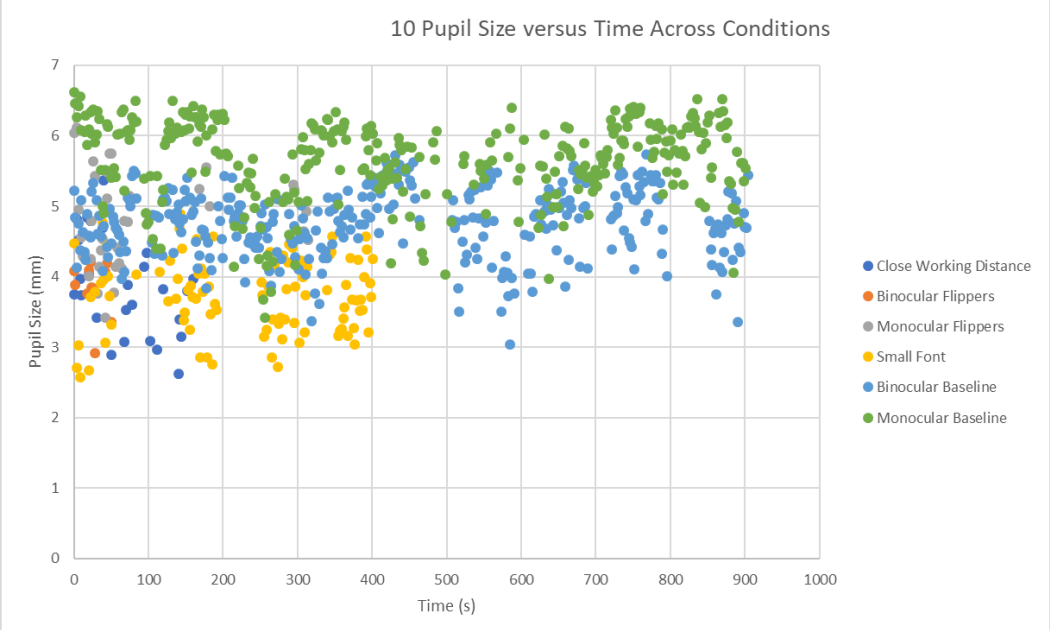
Graph 11.7

Participant 09 Pupil Size versus Time



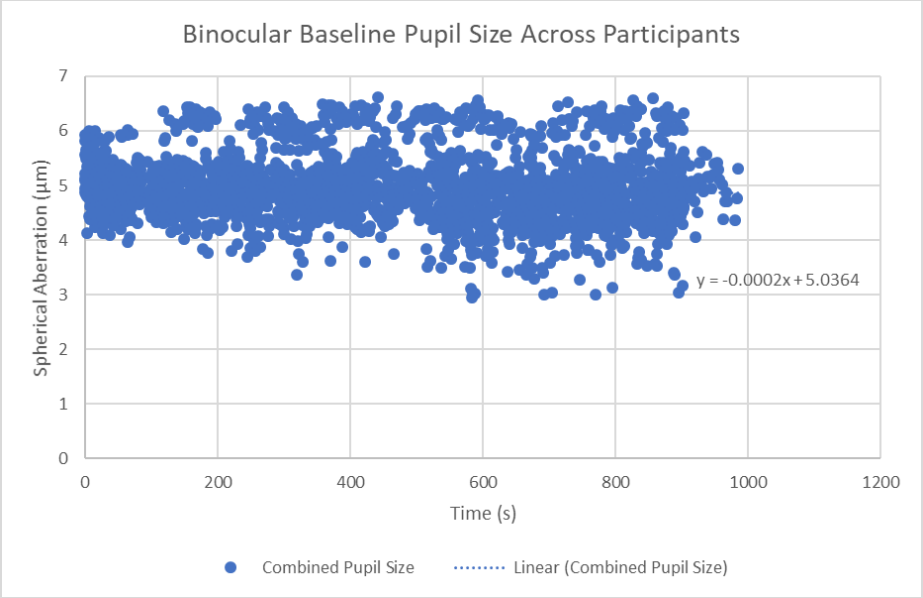
Graph 11.8

Participant 10 Pupil Size versus Time



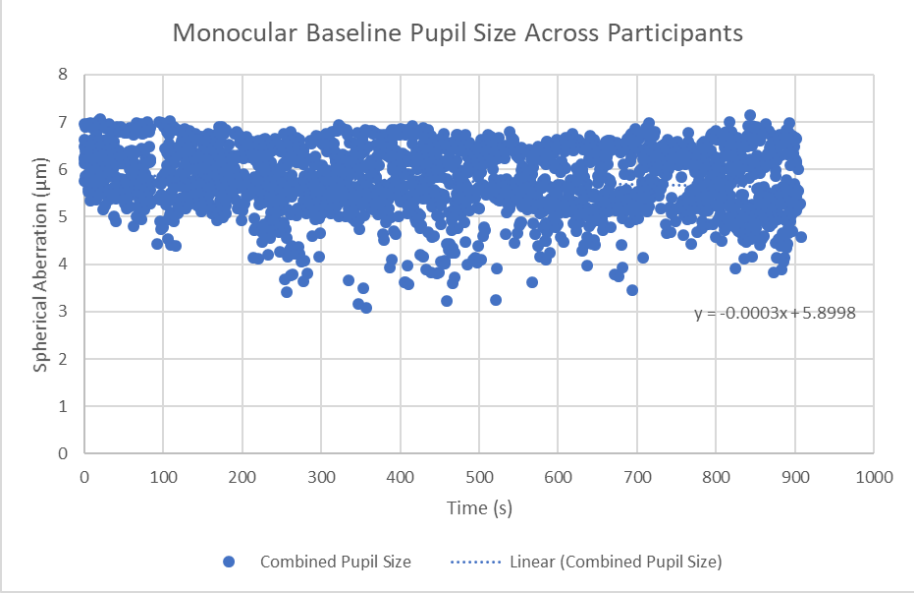
Graph 12.1

Binocular Baseline Pupil Size Across Participants



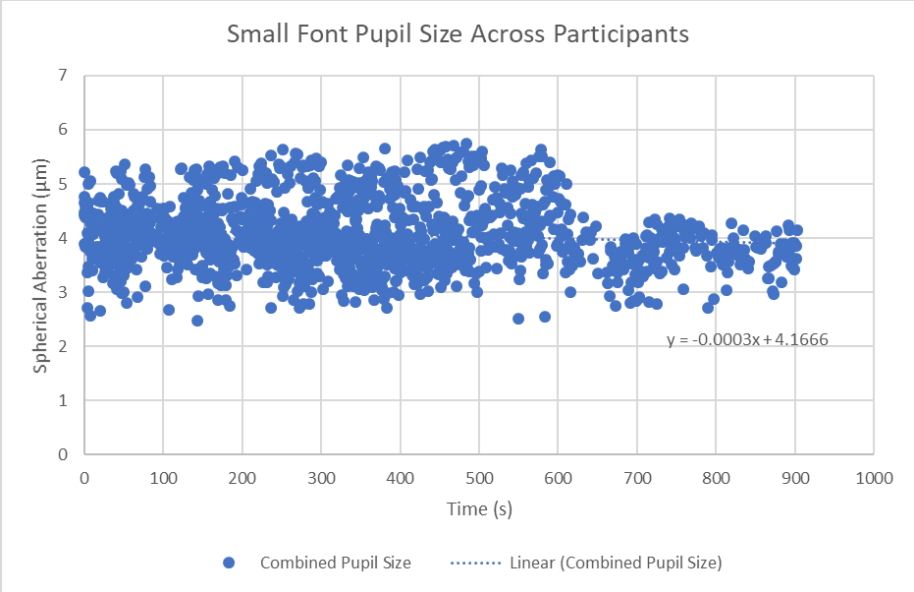
Graph 12.2

Monocular Baseline Pupil Size Across Participants



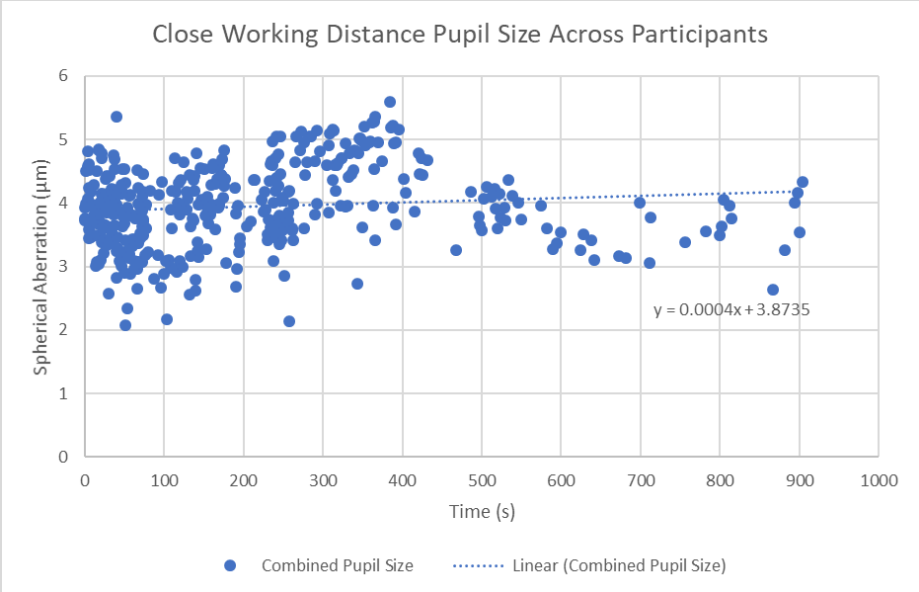
Graph 12.3

Small Font Pupil Size Across Participants



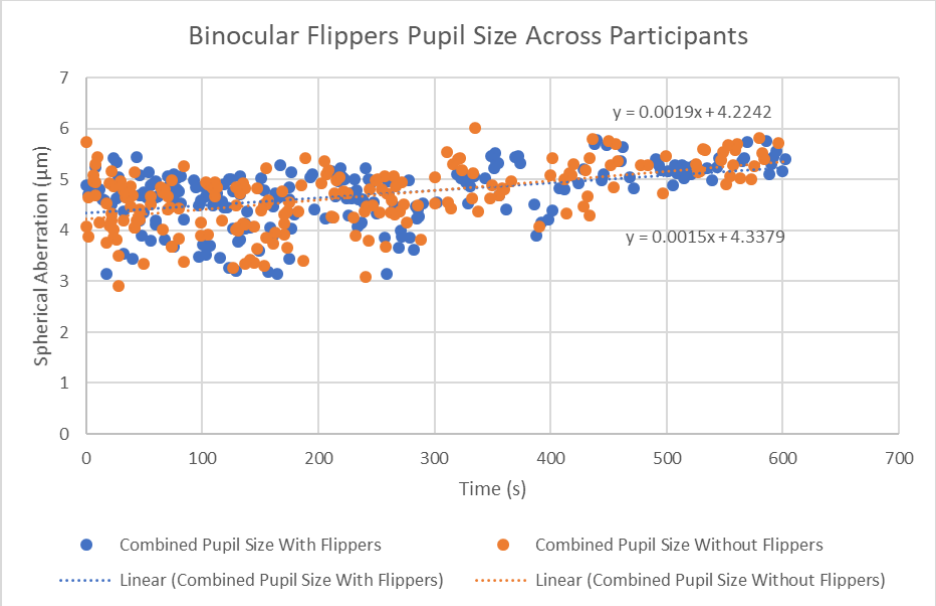
Graph 12.4

Close Working Distance Pupil Size Across Participants



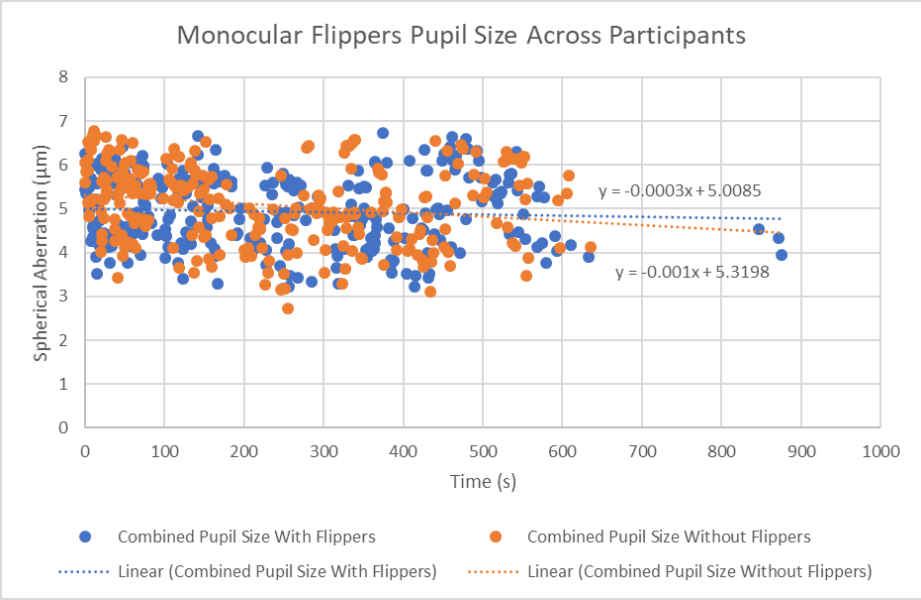
Graph 12.5

Binocular Flippers Pupil Size Across Participants



Graph 12.6

Monocular Flippers Pupil Size Across Participants



The slopes found on the preceding graphs may then be analyzed via t-test to determine if the slopes are significantly different from zero. This is presented in Table 13.

Table 13

One-sample Two-tailed T-Test; Ho (that there is no difference between the population mean and zero) is rejected if p<0.05.

Test Condition	**Slope**
Binocular Baseline	0.00002
Monocular Baseline	-0.0003
Small Font	-0.0003
Close Working Distance	0.0004
Binocular Flippers (With Flipper)	0.0015
Binocular Flippers (Without Flipper)	0.0019
Monocular Flippers (With Flipper)	-0.0003
Monocular Flippers (Without Flipper)	-0.001
Average	0.00024
Standard Deviation	0.000987
N	8
p	0.514

As the p-value of 0.514 is greater than 0.05, the null hypothesis is not rejected. The slopes are not statistically different from zero. This shows that as participants get increasingly fatigued over the duration of the tests, their pupil sizes remain stable.

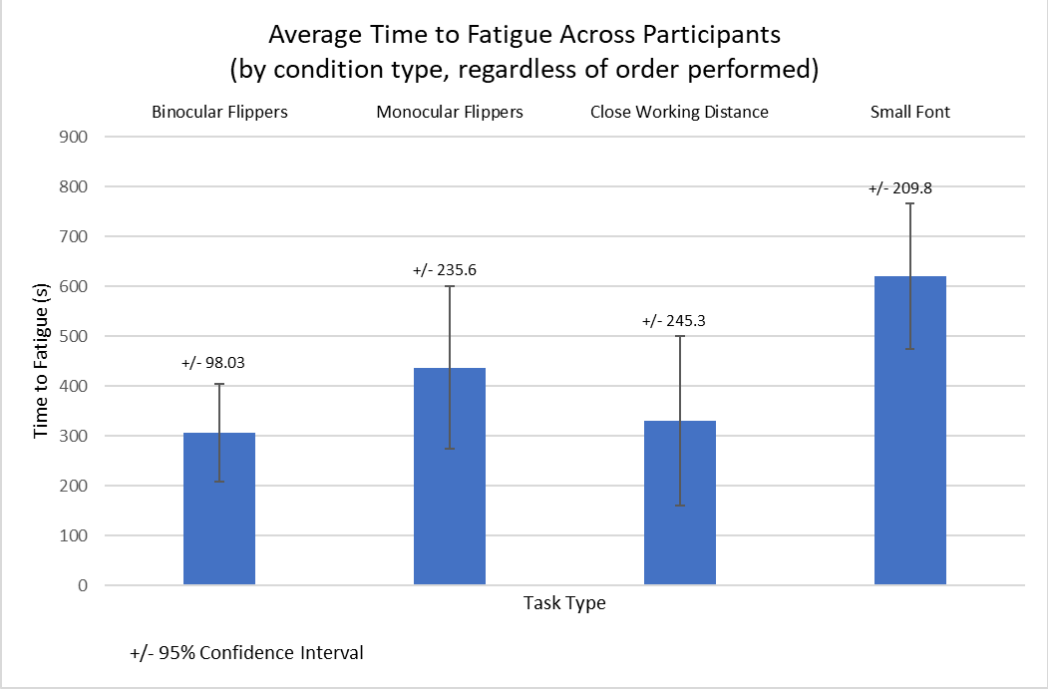
Go-Pro Camera Video Recording Data

The video camera utilized in this study allowed for accurate measurement of two important variables: (1) Time to fatigue, and (2) fissure height of the participant's eye during testing.

The duration of time to fatigue is presented in many of the graphs above, however, to more effectively view and compare between participants and conditions, the data may be separated into individual graphs.

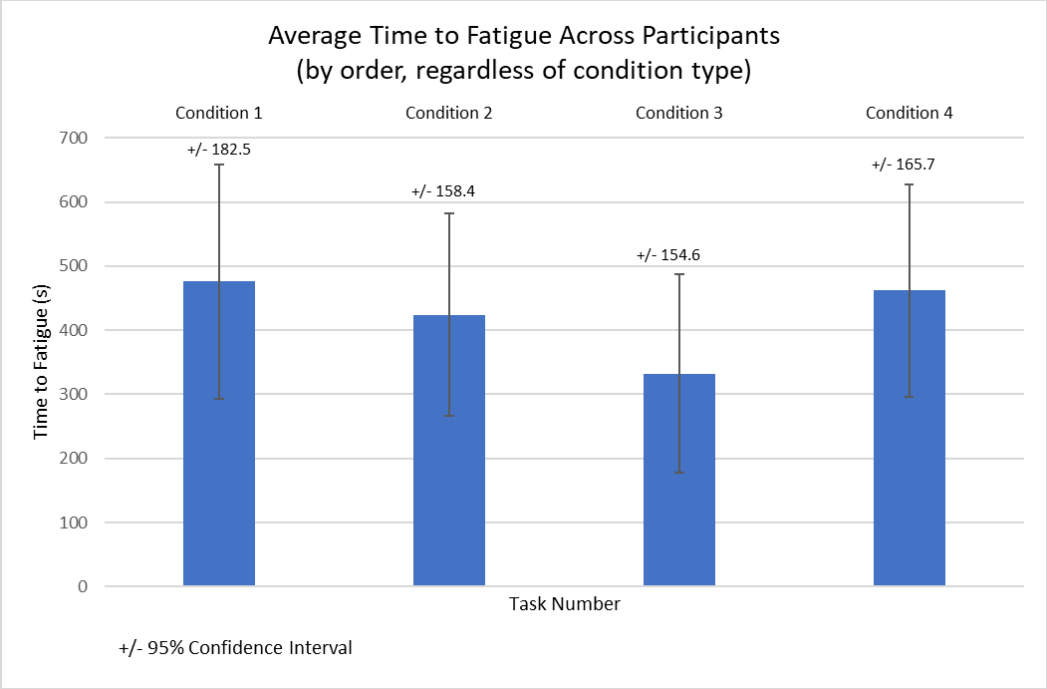
Graph 13.1

Average Time to Fatigue Across Participants (by condition type, regardless of order performed)



Graph 13.2

Average Time to Fatigue Across Participants (by order, regardless of condition type)



These graphs show that a condition that works to fatigue the subject appears to have a shorter duration of time. Further analysis of this data is relevant to determining if there is a statistical difference in time to fatigue based on the condition type or condition order. Tables 14 and 15 present this analysis.

Table 14

ANOVA Results; Ho (that there is no difference between the average time to fatigue based on condition type) is rejected if p<0.05.

	Binocular Flippers	Monocular Flippers	Close Working Distance	Small Font	Total
N	8	8	8	8	32
∑X	2456	3499	2639	4967	13561
Mean	307	437.375	329.875	620.875	423.781
$\sum X^2$	914086	1974407	1352109	3435967	7676569
Std Dev	151.2302	251.8593	262.2891	224.2705	249.4944

Source	SS	df	MS
Between	491895.8438	3	163965.281
Within	1437775.625	28	51349.1295
Error	443998.4063	21	21142.7813

F= 7.75514
p= .001133
Significant @ p<0.05

Table 15

ANOVA Results; Ho (that there is no difference between the average time to fatigue based on condition order) is rejected if p<0.05.

	Binocular Flippers	Monocular Flippers	Close Working Distance	Small Font	Total
N	8	8	8	8	32
∑X	3808	3395	2659	3699	13561
Mean	476	424.375	332.375	462.375	423.781
$\sum X^2$	2367746	1858753	1282231	2167839	7676569
Std Dev	281.6122	244.365	238.5809	255.6543	249.4944

Source	SS	df	MS
Between	100573.8	3	33524.61
Within	1829098	28	65324.92
Error	835320.4	21	39777.16

F= 0.84281
p= .485748
Not Significant @ p<0.05

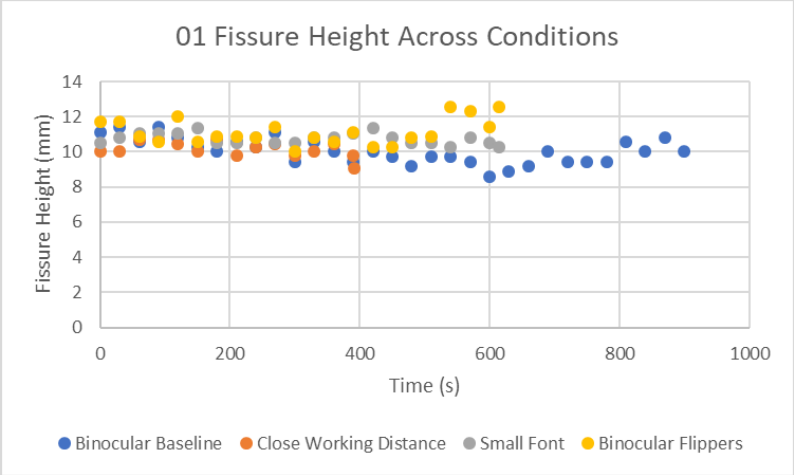
The result of significance by condition type and non-significance by condition order is an important distinction. This indicates that the order of condition type performance is irrelevant to the time to fatigue; it is the condition type that causes the participant to fatigue faster or slower.

Fissure height is the final measure collected for this study. Each participant's right eye was measured by the COAS aberrometer and was therefore blocked to the view of the Go-Pro camera. The left eye, however, could be monitored for fissure height during each test duration. No data was collected on fissure height for the monocular conditions (baseline and flippers), as the left eye was occluded during those tests. Measurements were captured at the beginning of the test (at time equals 0 seconds), every 30 seconds thereafter, and at the conclusion of the test.

Graphs 14.1 through 14.8 present each participant's fissure height during each of these trials.

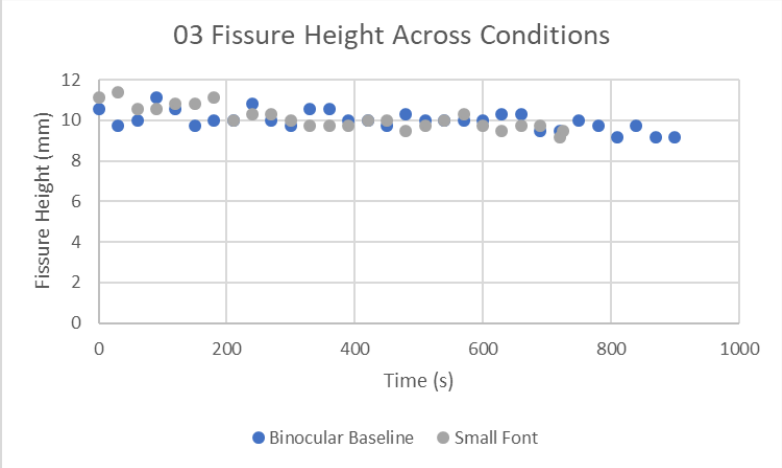
Graph 14.1

Participant 01 Fissure Height Across Conditions



Graph 14.2

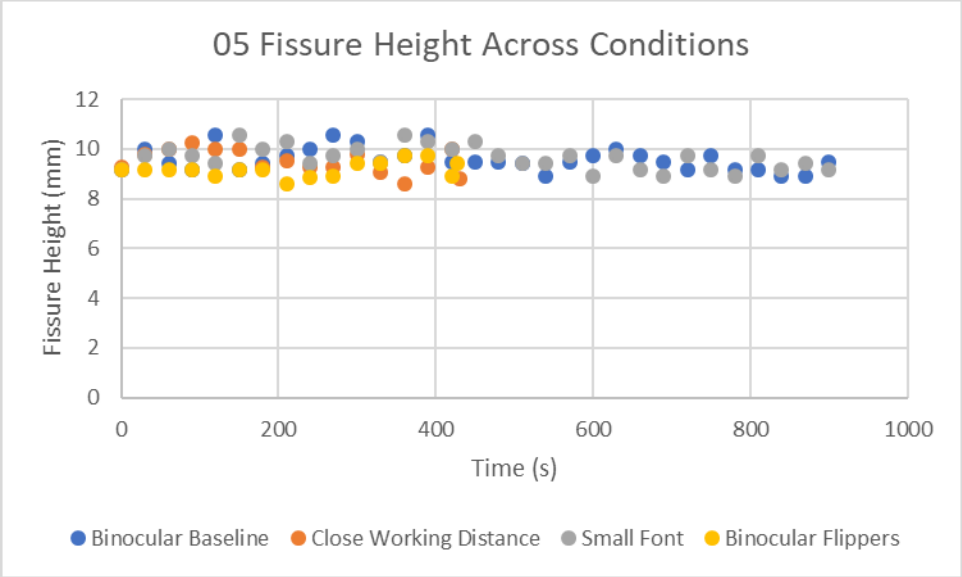
Participant 03 Fissure Height Across Conditions



The binocular flippers and close working distance conditions fissure height measurements are data missing at random for participant 03. The video data files were not saved.

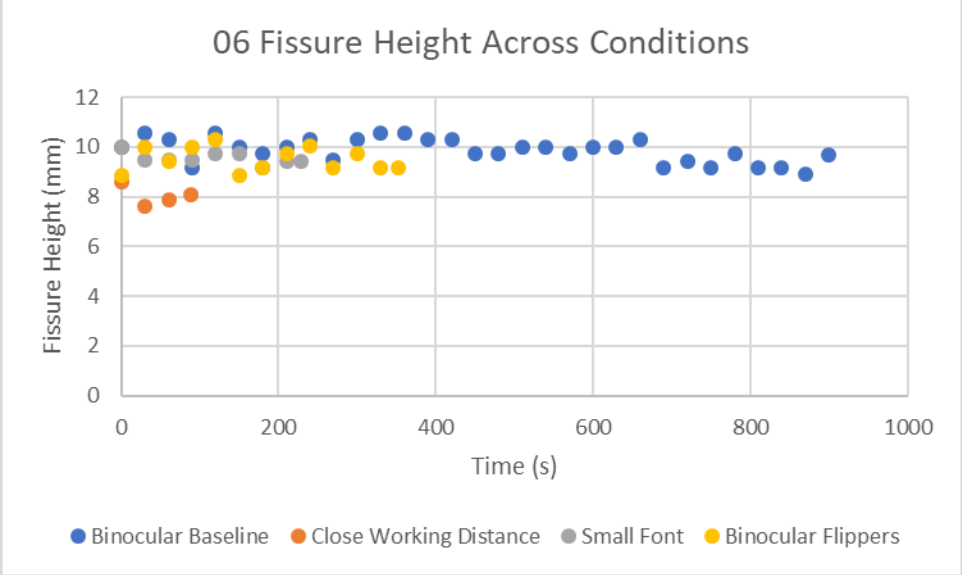
Graph 14.3

Participant 05 Fissure Height Across Conditions



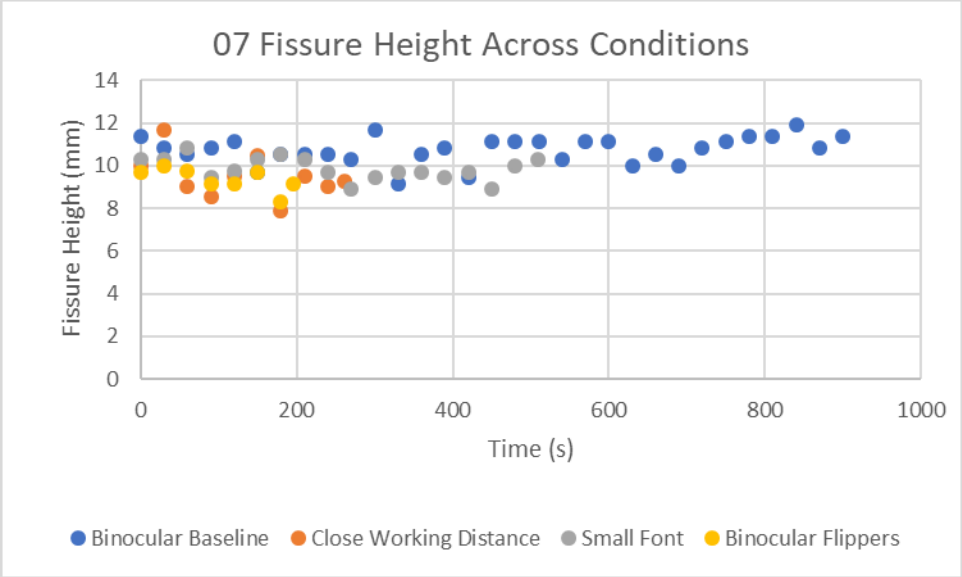
Graph 14.4

Participant 06 Fissure Height Across Conditions



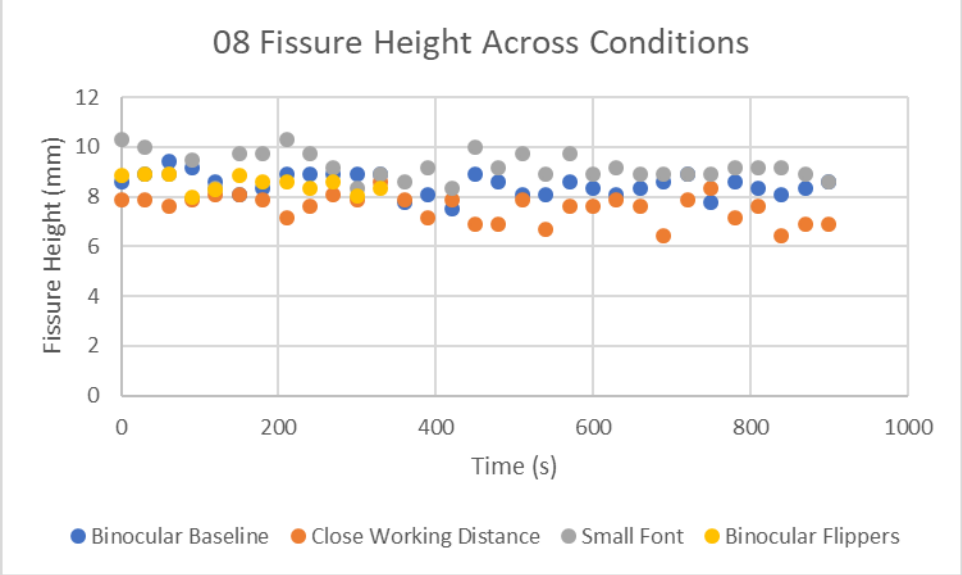
Graph 14.5

Participant 07 Fissure Height Across Conditions



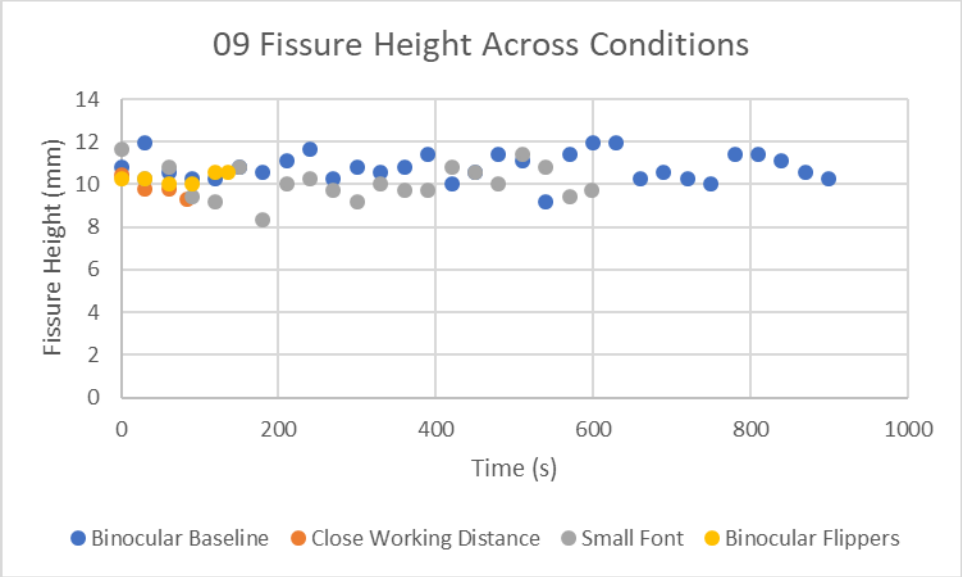
Graph 14.6

Participant 08 Fissure Height Across Conditions



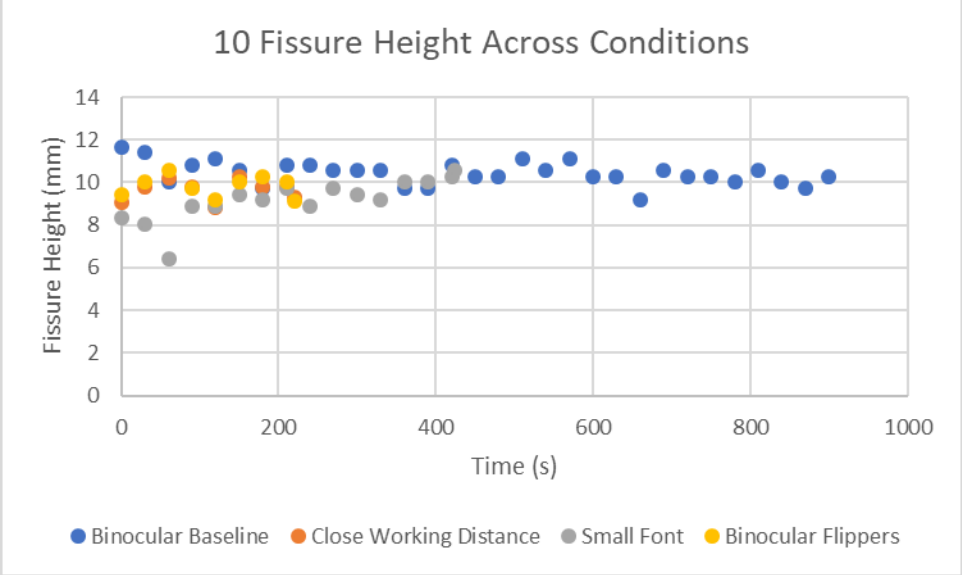
Graph 14.7

Participant 09 Fissure Height Across Conditions



Graph 14.8

Participant 10 Fissure Height Across Conditions



The shorter the task duration, the fewer measurements were taken. Nevertheless, in some, but not all instances, the participant's fissure height decreased as they fatigued. This is consistent with the act of squinting. Table 16 presents the two-sample t-test results for each participant in each condition, indicating whether there is a statistical difference between the fissure height measurements captured in the first quarter of test time and last quarter of test time.

Table 16

Two-tailed paired T-Test for two dependent means; Ho (that any difference in first-and last-quarter fissure height measures are due to chance) is rejected if p<0.0125

(Bonferroni correction was utilized to determine the p-value: alpha of 0.05 divided by 4 induction testing categories equals new p-value of 0.0125. The Blue data in the following graph represents non-significance at p>0.0125; Red represents significance at p<0.0125.)

Participant	Binocular Baseline	Small Font	Close Working Distance	Binocular Flippers
01	0.008	0.006	0.121	0.25
03	0.004	<0.001	No data	No data
05	0.114	0.014	0.07	0.132
06	0.002	0.494	0.842	0.728
07	0.142	0.226	0.339	0.185
08	0.108	0.037	0.049	0.017
09	0.715	0.917	0.315	<0.001
10	0.057	0.023	0.682	0.863

As may be seen in the graph above, only a few instances, and primarily in the binocular baseline category (where every participant was required to complete 15 minutes of testing) is the test result indicative of significant squint.

Finally, an exploration of any relationship between refractive state error and fissure height was performed. As these two measurements are unrelated except for their occurrence at a given point in time, a correlation analysis was performed. Table 17 reports R, the correlation coefficient found for each instance. Table 18 reports R-squared. Again, due to the ability of the video to capture only images of the participant's left eye, no monocular conditions are reported here.

Table 17

Correlation Coefficient between Refractive State Error and Fissure Height (red represents a correlation coefficient of at least +/- 0.5, indicating a strong correlation)

Participant	Binocular Baseline	Small Font	Close Working Distance	Binocular Flippers
01	0.565793	-0.30433	-0.40252	0.564211
03	-0.00205	0.651438	No Data	No Data
05	0.256379	-0.2347	-0.46362	-0.78449
06	0.418876	-0.52531	-0.93302	-0.41294
07	0.181212	0.194816	-0.80297	-0.81295
08	-0.46619	-0.28203	-0.52099	0.273257
09	0.23592	-0.04133	-0.76495	-0.98161
10	0.066247	-0.09281	-0.05747	-0.34999

Negative correlation indicates that as refractive state error increases, fissure height decreases. Positive correlation indicates that as refractive state error increases, fissure height also increases.

Table 18

Coefficient of Determination (R^2) between Refractive State Error and Fissure Height (red represents R^2 values of over 50%)

Participant	Binocular Baseline	Small Font	Close Working Distance	Binocular Flippers
01	32.01215	9.261738	16.20188	31.83339
03	0.000421	42.43713	No Data	No Data
05	6.573015	5.508215	21.49468	61.54216
06	17.54569	27.59472	87.05287	17.05183
07	3.283771	3.795347	64.4756	66.08927
08	21.73309	7.953998	27.14304	7.466926
09	5.565836	0.17078	58.51429	96.3552
10	0.438862	0.861296	0.330329	12.24963

This table shows the percentages at which the variance of refractive state error is related to the variance of fissure height. Those with strong R^2 values (highlighted in red) indicate that their respective fissure heights and refractive state errors are closely linked.

The strongest coefficient values indicate a negative correlation between refractive state error and fissure height. Knowing from previously reported data (see Table 9) that as participants fatigued, their refractive state errors increased; therefore, with increasing fatigue and refractive state error, fissure height decreases. This is indicative of squinting.

Discussion

The two-visit organization of this study ensured that the participant selection could be isolated to groups with or without specific parameters. Especially important, due to the small number of participants in this pilot study, the participant selection required isolation of individuals with no pre-existing medical, binocular vision, dry eye or refractive problems which could confound the data collected. The screening-visit proved successful in facilitating the rapid disqualification of participants who did not meet the inclusion/exclusion criteria set for this study. Ultimately, two prospective participants were disqualified from completing the study based on the results of the screening-visit. Both participants were found to have pre-existing dry eye symptoms, as indicated by a CLDEQ-8 score of over 12.[85,86] The remaining eight participants were an adequate number to complete the gathering of pilot data.

While no participants were disqualified due to refractive errors outside of the range presented in the inclusion criteria, a careful refraction with and without cycloplegia was performed at the screening-visit. This purpose was to ensure the contact lenses selected for the study-visit would neither help (if under-minused) or hinder (if over-minused) the participant's performance in the testing scenarios. Tropicamide 1% was selected for use as the cycloplegic agent in this study rather than cyclopentolate 1%, as studies have shown minimal to no difference in cycloplegic refractions performed with both eyedrops, and tropicamide 1% has a

[85] Chalmers RL, Keay L, Hickso-Curran SB, Gleason WJ. Cutoff score and responsiveness of the 8-item Contact Lens Dry Eye Questionnaire (CLDEQ-8) in a Large daily disposable contact lens registry. Contact Lens and Anterior Eye. 2006 Oct. 39(5): 342-352.
[86] Chalmers RL, Begley CG, Moody K, Hickson-Curran SB. Contact Lens Dry Eye Questionnaire-8 (CLDEQ-8) and Opinion of Contact Lens Performance. Optometry and Vision Science. 2012 Oct. 89(10): 1435-1442.

faster onset of maximum cycloplegic effect (at 30 minutes).[87,88] The study-visit was performed at least 24 hours after the screening-visit to ensure the Tropicamide 1% dilation eyedrop used to gather accurate refractive testing data was no longer active.[89] Biofinity sphere contact lenses (CooperVision, Fairport, NY) fit for each participant's optimal distance refraction were selected for use in this pilot study. This specific lens was selected for two reasons: (1) Prior studies related to asthenopia performed in the Clinical Optics Research Laboratory at Indiana University utilized the Biofinity sphere lens, as it is designed with CooperVision's proprietary Aberration Neutralizing System™, which are aspheric optics designed to "minimize spherical aberrations inherent in both the lens and eye."[90] As the human eye contains positive spherical aberration, the induction of controlled levels of negative spherical aberration in the manufacturing of contact lenses has been found to improve visual acuity.[91,92] (2) It was known that the Biofinity Energys contact lens was nearing its product launch. Biofinity contact lenses (with the same material, base curvature, diameter, and wear regimen as Energys) would provide an excellent control lens in a future study.

The purpose of the study-visit design was to allow statistical analysis which separated known sources of variation from random error. By using the specialized randomization technique

[87] Lin LKL, Shih YF, Hsiao CH, Su TC, Chen CJ, Hung PT. The Cycloplegic Effects of Cyclopentolate and Tropicamide on Myopic Children. Journal of Ocular Pharmacology and Therapeutics. 2009 Jan. 14(4): 332-335.
[88] Hofmeister EM, Kaupp SE, Schallhorn SC. Comparison of tropicamide and cyclopentolate for cycloplegic refractions in myopic adult refractive surgery patients. Journal of Cataract & Refractive Surgery. 2005 Apr. 31(4): 694-700.
[89] Mydriacyl Product Information. Available at: http://www.medsafe.govt.nz/profs/datasheet/m/Mydriacyleyedrop.pdf. Accessed: September 2, 2017.
[90] Biofinity: Improving the Way People See, Whatever Their Visual Needs. October 10, 2017. Available At: https://coopervision.com/practitioner/our-insights/product-spotlight/biofinity-improving-way-people-see-whatever-their-visual-needs. Accessed: October 27, 2019.
[91] Rae SM, Allen PM, Radhakrishnan H, Theagarayan B, Price HC, Sailaganathan A, Calver RI, O'Leary DJ. Increasing negative spherical aberration with soft contact lenses improves high and low contrast visual acuity in young adults. Ophthalmic & Physiological Optics. 2009 Oct. 29: 593-601.
[92] Wagner S, Conrad F, Bakaraju RC, Fedtke C, Ehrmann L, Holden BA. Power profiles of single vision and multifocal soft contact lenses. Contact Lens & Anterior Eye. 2015 Feb. 38(1):2-14.

of the Latin square, the number of participants required to complete the experiment were kept to a minimum, while the analysis accounted for variance between subject and order. The ANOVA table for a typical Latin square analysis may be seen in Table 19:[93]

Table 19

ANOVA Table for Latin Square

Source	**df**	**SS**	**MS**	**F**
Rows	r - 1	SSR	SSR/(r-1)	MSR/MSE
Columns	r - 1	SSC	SSC/(r-1)	MSC/MSE
Treatments	r - 1	SST	SST/(r-1)	MST/MSE
Error	(r-1)(r-2)	SSE	SSE/((r-1)(r-2))	
Total	r^2-1	TSS		

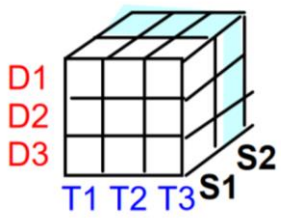
The benefit to this experiment of utilizing the Latin square statistical design was that the sum of squares of the rows and columns are accounted for separately, and not incorporated into the error term. This reduced the expected size of the MSE variable (treatment/error degrees of freedom), thus enlarging the MST/MSE total value, increasing the likelihood of reaching significance and finding that H_i is true. Additionally, by having increased the number of participants to 8 from the requisite 4, the ANOVA table changed slightly to further decrease the error variable (MSE). The ANOVA table for the repeated Latin square was presented as Table 4, where the only change from the traditional Latin square design may be seen by the multiplication by 2 of the degrees of freedom in the error row: 2(r-1)(r-2). As considerable variability was expected between participants, the repeated Latin square design was utilized, to increase the degrees of freedom for experimental error.[94] This may be visualized in Figure 4, where rows

[93] Dubcovsky, J. Double Block Designs: Latin Squares.
[94] Ibid.

(D), columns (T) and the repeated Latin square (S) show how the additional subjects (added to reduce experimental error) are randomized in repetition, sharing the same rows and columns. The randomization scheme utilized in this experiment (Table 3) shows this same design.

Figure 4

Repeated Latin Square



As with any Latin square designed experiment, the test is not particularly sensitive to handling significant interactions between the variables presented in the rows and columns, as interactions inflate the MSE (error term) resulting in decreased likelihood of reaching statistical significance.[95] Having made the assumption of no interaction between these variables, this analysis should result with enough power to come to a conclusion.

The study-visit presented four testing scenarios for future research: to explore which asthenopia induction testing method as analyzed by measurement of defocus, pupil size, and spherical aberration by the COAS aberrometer would provide the easiest repeatability and best comparison to baseline data, to allow for objective measurement if asthenopia were relieved via use of an optical device. More specifically, time at task and refractive state error and variability (measured via accommodation) were the most important factors to consider, as it would be expected that a successful task would have a higher variability, shorter duration of time, and

[95] Ibid.

potentially larger refractive state errors or errors that would increase over the test duration. Special considerations needed to be made to replicate the induction techniques performed in previous literature, while allowing for effective use of the COAS aberrometer.

The -3.00 DS binocular flipper was selected to mimic traditional accommodative facility testing in an optometric setting, and a -3.00 DS trial lens alone was selected for the monocular flipper condition.[96,97] The study method of flipping between a minus lens and no lens was designed to eliminate the possibility of a COAS reading in between the induced stress and relaxed condition (e.g. if the participant was half-way through flipping a traditional +/-2.00 DS flipper, a reading would be considered invalid, as too many variables exist in that moment to warrant investigation of that data point). A -3.00 DS lens was selected for the condition as a stimulus to accommodation, to be contrasted with "neutral," that is, no lens. Though the purpose of both flipper conditions was to fatigue a participant's accommodative facility, they were tested separately in this experiment just as they are tested separately in a clinical setting. The binocular flipper purpose was to test the ability to stimulate and relax accommodation while maintaining convergence, while the monocular flipper tests the accommodative system alone.

The small font condition replicated the 5-point font at 60 cm working distance that was presented as the standard in previous literature.[98] The replication was accomplished by mathematically matching the font size of the Mahjong tile image to 1 mm height (for the mathematical conversion, see Appendix 5).

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[96] Allison C. Eyedentify Your Patient's Efficiency Problems. Review of Optometry. June 15, 2005. Available at: https://www.reviewofoptometry.com/article/eyedentify-your-patients-efficiency-problems. Accessed on: September 4, 2017.

[97] Chen A, Borsting E, Lao M, Yang J. Accommodative Facility Measured by +/-2.00 Flipper and Dioptrically Equivalent Target Distances. Abstract. Presented at: Annual Meeting of the American Academy of Optometry; October 2010; San Francisco, CA, USA.

[98] Gowrisankaran S, et al. Eyelid Squint Response to Asthenopia-Inducing Conditions.

The close working distance condition brought the stimulus screen to a 20 cm working distance while a +5.00 DS pair of spectacles was utilized rather than a trial lens. The goal was to closely match the participant's interpupillary distance to avoid inducing any prismatic effects (which would have invalidated the data by inducing variable vergence strain that would differ between participants). This set up differed slightly from previous studies, which utilized a 16.7 cm working distance and +6.00 DS spectacles.[99,100] The 20 cm working distance utilized in this experiment was required due to the presence of the COAS, as binocularity was lost with a closer working distance as the instrument blocked view of part of the stimulus screen.

As with any game used as a stimulus item, as the study progressed and more puzzles were completed, it was expected that the participant's skill at solving the game puzzles would improve.[101] Therefore, for this study, it was deemed necessary to find a way to minimize the effect participant game skill and adaptation would have on the results. After consideration, it was determined that a randomized matching game such as Mahjong would provide less of this effect.[102]

The Go-Pro Hero 4 silver edition digital camera required special considerations to its efficacy as a tool in capturing data on fissure height. Fortunately, since the data being compared is of ratios between measurements, the pixel length change due to the addition of lenses (for instance, the -3.00 DS lenses in the flipper task, or +5.00 DS lenses in the close working distance task) is irrelevant. For example, measured in Photoshop, 77 pixels are counted in diameter of an

[99] Ibid.
[100] Sheedy JE, et al. Is All Asthenopia the Same?
[101] Eversheim U and Bock O. Evidence for Processing Stages in Skill Acquisition: A Dual-Task Study. Learning & Memory. 2001 Jul. 8(4): 183-189.
[102] Järvelä S, Ekman I, Kivikangas JM, Ravaja N. A Practical Guide to Using Digital Games as an Experiment Stimulus. Transactions of the Digital Games Research Association. 2014 Mar. 1(2). Available at: http://todigra.org/index.php/todigra/article/view/16/23. Accessed September 3, 2017.

image of a 1 cm distance on a PD stick at the 22 cm working distance. If a +2.00 DS lens is placed directly in front of the PD stick, the pixels increase to 81 per 1 cm distance of the imaged PD stick. A -2.00 DS lens results with 75 pixels. A +6.00 DS lens results with 83 pixels. Put simply, a percentage change is required for the analysis of images across testing scenarios, as the number of pixels, or lengths, is not directly comparable without factoring in the shift due to the lenses used in each testing scenario. While the testing scenarios presented in this study would not all lend themselves to squint, this analysis could be made using the recorded data from the GoPro camera, to confirm the repeatability of past squint study findings. Following the precedent set by Gowrisankaran's 2007 study on "Eyelid Squint Response to Asthenopia-Inducing Conditions," high quality image capture collected of the participant's left eye during the testing scenarios could provide information on fissure height (see Graphs 14.1-14.8). Gowrisankaran's results focused on contracture of the orbicularis oculi, which was found to a small degree in all asthenopia-inducing conditions (including those repeated in this study) but statistically significant squint was only seen in instances where squinting would truly improve visual clarity via the pinhole effect.[103] Comparatively, in this study few instances of statistically significant squint were found (see Tables 16, 17, and 18). However, in the cases where squint was seen, it correlates with the expected pattern that with increasing fatigue and refractive state error, squinting too is found to increase.

A fifteen-minute wash-out period of rest was in place after each asthenopia induction testing scenario, to allow for accommodative and convergence fatigue to recover. This time was lengthened from what has been previously performed in the literature, where a brief five-minute

[103] Gowrisankaran S, et al. Eyelid Squint Response to Asthenopia-Inducing Conditions.

wash-out period was determined to be "sufficient based on symptom scores".[104,105] The lengthened rest period was utilized for this procedure to ensure adequate recovery regardless of the severity level of asthenopia achieved in the testing phase. Success of this fifteen-minute wash-out period is further expressed in the time to fatigue analysis (see Tables 14 and 15) which show that time to fatigue was impacted solely on the condition type, and that the order of conditions performed had no effect. Interestingly, the symptom severity scale results did show a replicable pattern consistent with adaptation. The results (which may be seen in graphs 2.1 through 2.8 in the Results section) show some negative values in the change in severity scale scores. This indicates that after experiencing discomfort during a task, when the uncomfortable stimulus was removed (that is, the task completed) the participant subjectively felt "better" than they had before the testing was initiated. An example of this phenomenon experienced in daily life is of simple light adaptation: if one exits a dimly lit room into bright sunshine and then returns to the room, it will appear darker than it initially had, due to light adaptation.

Non-invasive tear break up time (NITBUT) measurements were performed before and after each testing scenario. The statistical analysis (presented in tables 5.1, 5.2, 6.1 and 6.2 in the Results section) all show p-values of greater than 0.05. This conclusively agrees with the null hypothesis that any change in NITBUT is due to chance. This replicates previous dry eye studies that reveal no correlation between the signs and symptoms of dry eye.[106] This proves that dry eye may be excluded as a factor in the asthenopia induced in this experiment, allowing the COAS data to be reviewed on its own.

[104] Ibid.
[105] Gowrisankaran S, et al. Eyelid Squint Response to Asthenopia-Inducing Conditions.
[106] Bartett HD, Keith MS, Sudharshan L, Snedecor SJ. Associations between signs and syptoms of dry eye disease: a systematic review. Clinical Ophthalmology 2015, 9:1719-1730.

The study-visit was designed to explore the four asthenopia induction methods, described above, to determine which would be the most promising scheme for future investigation. This was performed by analyzing the data subsets of refractive state, spherical aberration and pupil size data as captured by the COAS Aberrometer for each participant in each of the four asthenopia induction methods.

As a control, baseline data in all three subsets was first captured for each task condition to be compared to. This data was collected by having each participant perform the task stimulus for a full 15-minute session and was performed in both binocular and monocular conditions. Distance pre- and post-test data was collected with a focal point at optical infinity, to confirm (1) that the participant's accommodative system was properly functioning and (2) that the COAS was detecting defocus measurements in accordance with the task set up alone. See Appendix 6 for graphs which concur with the expectations highlighted in the previous sentence. Additionally, a short monocular and binocular post-test data set was collected for comparison with the monocular and binocular baseline data, to ensure that the proposed control data could be used as such. These post-test graphs may be viewed in Appendix 7.

Analysis of refractive state over time showed similar results across participants (see graphs 3.1a-f through 3.8a-f in the Results section).

Defocus data collected centrally (paraxial accommodation) and minRMS are only exactly aligned when negative spherical aberration is at zero, which may only occur when pupils are very small. A primary example of this finding is in the close working distance condition. The greater the difference between the paraxial and minRMS readings, the larger the amount of negative spherical aberration. In contrast to the close working distance condition, a separation of the paraxial and minRMS data is well highlighted in the monocular baseline condition.

Measurements of paraxial accommodation are very accurate as to the participant's true point of focus. While most often it was found to be directed exactly at the target stimulus location, some tasks resulted with an offset. The close working condition universally resulted with a slight over-accommodation. The increased convergence demand in the close working distance condition may have increased the accommodative response over what was strictly necessary; when the convergence demand was eliminated in the monocular conditions, accommodation was always found to be less than the target stimulus demand. Interestingly, the distance baseline and post-test data revealed a similar trend of a subtle over-accommodation (see Appendix 6. For optimal subjective distance viewing, myopic individuals often request slightly higher amounts of minus-lens prescriptions than is strictly necessary based on their objective optical requirement. As every effort was made in this study to fully and accurately correct the participants' refractive errors, subjective under-correction may be expected when viewing a distance target without effects of a cycloplegic agent. Under all other testing conditions (tasks, baseline, and post-test data) the paraxial accommodative data revealed either a true focus on the target stimulus, or a small under-accommodation. This is consistent with a clinically normal lag of accommodation in the pre-presbyopic population, which is considered +0.50 to +0.75 D of lag.[107]

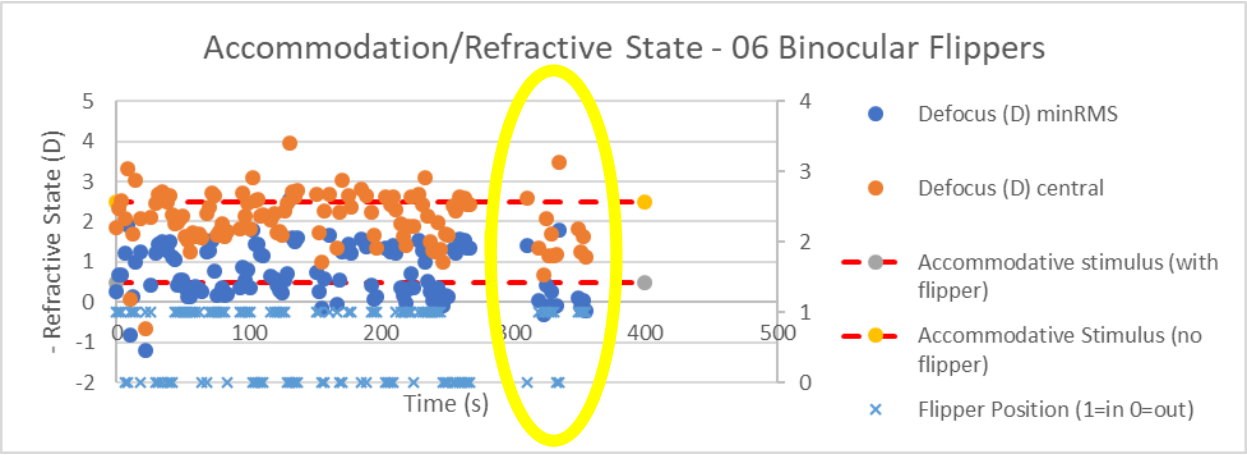
The flippers conditions revealed a more complex analysis of results. Over time, an increase in accommodative relaxation was seen with the insertion of the flippers, with an increased variability of results but generally low gain of the accommodative response. While this may be expected in patients with a high CA/C ratio (dominant vergence control of accommodation), the screening protocol confirmed that all participants had normal

[107] Benjamin WJ. Borish's Clinical Refraction. 2nd ed. (Oxford: Butterworth-Heinemann-Elsevier, 2006), 682-764.

accommodative and vergence systems. Additionally, in some instances the participants' accommodative response moved in the incorrect direction (e.g. increasing accommodation when the flippers were removed, and accommodation should have relaxed). A clear example of his is may be seen in the circled portion of Graph 15.

Graph 15

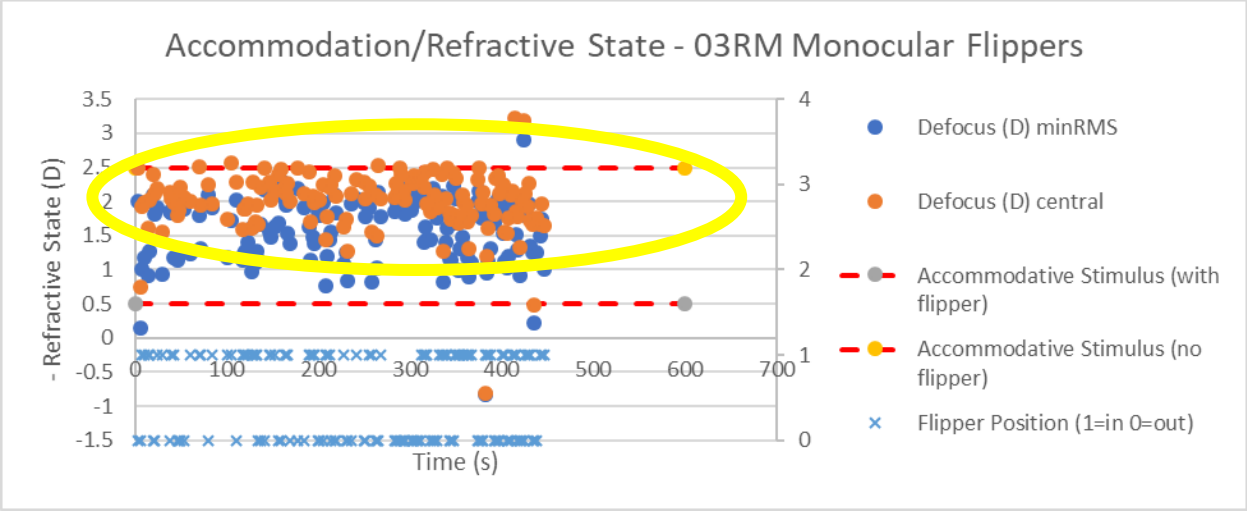
Copy of Graph 3.4d with Illustration of Incorrect Accommodative Response



Indeed, in the monocular flippers condition (Graphs 3.1-3.8e), when the convergence cues were removed, on most trials the accommodation is not relaxed at all (see paraxial data close to the 2.50 D stimulus). A clear example of his is seen in Graph 16.

Graph 16

Copy of Graph 3.2e with Illustration of Accommodative Response close to 2.50 D



What seems most intriguing about the results of both binocular and monocular flipper conditions is that a simple accommodation (+) / relaxation (-) response was not found. In a model eye, the accommodative system would compensate for the full power of the lens flipper, and measurement of defocus would not change. After fatiguing, the time to achieve clarity (regardless of amount of lag) will increase in duration, and eventually will not be achieved (see Figure 5).

Figure 5

Schematic of the Expected Pattern of Ocular Fatigue in a Flipper Task

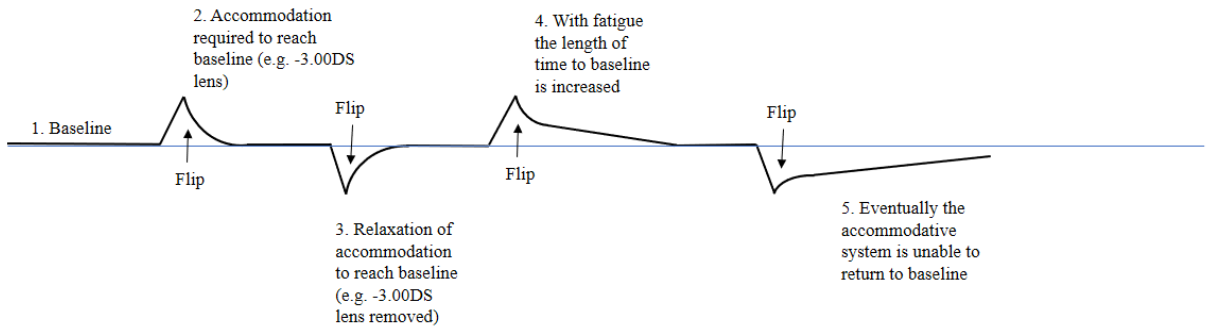
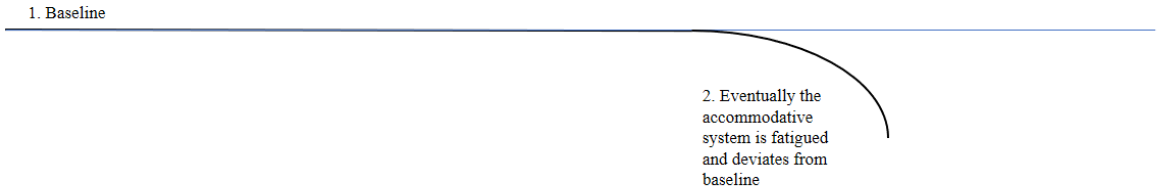


Figure 6

Schematic of the Expected Pattern of Ocular Fatigue in a Close Working Distance or Small Font Task



In comparison to the binocular and monocular flipper conditions, the stimulus in the small font and close working distance tasks kept a stable accommodative stimulus in place. Rather than the accommodation and relaxation changes expected with the lens flipper condition, a slow increase in defocus would be expected as the participant's accommodative and convergence system fatigued. While a subtle trend toward increased accommodative lag may be seen overall across the tasks, it was not a pronounced drop off-of accommodative ability that immediately preceded the stopping of the task due to "100% barely tolerable eyestrain" being achieved.

Refractive state error (determined as the actual refractive state error found by the COAS aberrometer minus the expected refractive state error indicated by the accommodative stimulus presented in the test) was consistent across participants, showing that as participants became increasingly fatigued over the duration of the tests, their refractive state errors increased. Further analysis of these measures indicates that with fatigue, the total refractive state error variance across conditions also increases. However, comparing variances within each condition revealed that variance does not increase over the duration of each test. Nevertheless, the proof that this increase in variability is consistent across participants over the duration of each test concurs with one of the primary outcome expectations.

Before analyzing any of the spherical aberration results, it should be highlighted that the finding of negative spherical aberration across participants in all conditions was a surprising result, as the human eye naturally has positive spherical aberration. There are two likely reasons for this finding: (1) While spherical aberration is typically positive for unaccommodated eyes,[108] as eyes accommodate, spherical aberration becomes increasingly negative.[109] (2) As described earlier in this section in the paragraph describing the selection of the Biofinity sphere lens for this study, past studies utilizing Shack-Hartmann wavefront aberrometry (first presented by Kollbaum et al, 2008)[110] have identified that many soft contact lenses, including the Biofinity sphere, have inherent negative spherical aberration.[111] The negative spherical aberration present in the Biofinity sphere varies with lens power, with increasing amounts of negative spherical

[108] Thibos LN, Hong X, Bradley A, Cheng X. Statistical variation of aberration structure and image quality in a normal population of healthy eyes. JOSA A. 2002. 19(12):2329-2348.
[109] Thibos LN, Bradley A, López-Gil N. Modelling the impact of spherical aberration on accommodation. Ophthalmic and Physiologic Optics. 2013 Feb. 33(4):482-496.
[110] Kollbaum P, Jansen M, Thibos L, and Bradley A. Validation of an off-eye contact lens Shack-Hartmann wavefront aberrometer. Optometry and Vision Science. 2008 Sep. 85(9):E817-E828.
[111] Wagner S, et al. Power profiles of single vision and multifocal soft contact lenses.

aberration with increasingly minus refractive power.[112] Table 20 presents the refractive correction needed for the eye measured by the COAS Aberrometer for each participant.

Table 20

Biofinity Sphere Right Eye Contact Lens Powers Utilized

Participant	Right eye (D)
01	-2.50
03	-4.25
05	-1.25
06	-2.00
07	-2.25
08	-2.75
09	-4.25
10	-1.50

Based on the lenses used, one might infer that participants 03 and 09 would have a greater amount of negative spherical aberration than the other participants. In a comparison of means between participants 03 and 09, their p-value is 0.2491, which is >0.05, indicating that there is no statistical difference in the average spherical aberrations between the participants with the highest myopic refractive error. Table 21 presents this same comparison of means across the other participants.

[112] Ibid.

Table 21

Comparison of mean spherical aberration values between participants 03 and 09 and the other test subjects; Ho (that any difference in average spherical aberration is due to chance) is rejected if p<0.05) (Blue represents non-significance at p>0.05; Red represents significance at p<0.05.)

Participant	P-value for comparison to Participant 03	P-value for comparison to Participant 09
01	0.0014	0.541
05	0.3783	0.4001
06	0.0012	0.0074
07	0.5753	0.3049
08	0.0198	0.7999
10	0.6557	0.1501

With the knowledge that no statistical difference exists between the average spherical aberration of participants 03 and 09, it is only participant 06 that results with a true difference in mean spherical aberration. While participant 06 has a refractive error of less than half of the highest prescription, it is not the lowest refractive error present in this study. Those belong to participants 05 and 10, both of whom show no statistical difference in average spherical aberration with the highest refractive errors. These results indicate that the amount of negative spherical aberration induced by the Biofinity contact lens may be considered equal across participants for the purposes of this study. Ultimately, while it is possible that the level of negative spherical aberration present in the Biofinity Sphere contact lens could have subtly impacted each participant's results, this would vary based on the individual's naturally occurring spherical aberration which was not measured in this study.

Knowing that negative spherical aberration is now expected for all participants, variations in the amount of spherical aberration may be considered. In the human eye, variations in the amount of spherical aberration are found in response to two factors: one, changing pupil size, and two, during accommodation due to flexure of the crystalline lens.

An increase in pupil size correlates with an increase in spherical aberration. This is corroborated by all spherical aberration data analyzed: average spherical aberration (Graphs 7.1-7.8), spherical aberration versus time (Graphs 8.1-8.8 and 9.1-9.6) , and spherical aberration versus pupil size (Graphs 10.1-10.8).

The most pronounced example in the average spherical aberration data is the close working distance condition, which caused a triad of involuntary ocular responses in all participants: convergence, accommodation, and miosis. The miosis caused lower levels of negative spherical aberration to be found in the close working distance condition than all other tasks, across all subjects (see graphs 7.1-7.8 in results section).

Graphs of spherical aberration versus time and pupil size versus time (see plots 8.1-8.8 and 11.1-11.8, respectively) showed largely static (horizontal) trends for each condition. This was proven in Tables 12 and 13, which show that across conditions even as participants became fatigued, their spherical aberration and pupil size measures remained stable. These results express that the greatest factor affecting spherical aberration was pupil size.

Finally, as spherical aberration is a known wavefront characteristic of the eye that varies with the fourth power of the pupil radius, a two-fold change in pupil size results with at 16-fold change in spherical aberration. This correlation can be clearly seen (Graphs 10.1-10.8) showing an increase in spherical aberration with an increase in pupil size.

Variability of spherical aberration with accommodation is more complex. Studies have shown that primary spherical aberration decreases during accommodation.[113] Additionally, as pupil size and accommodation are inextricably linked, in can be expected that with increased accommodative demand (e.g. with -3.00 DS flippers in the binocular and monocular flippers condition, which resulted in a +3.00 DS accommodative demand to the eye) that negative spherical aberration would decrease during flipper use due to the miosis inherent with the accommodation. However, a decrease in negative spherical aberration with increased accommodative demand was not always found to be the case in the flippers conditions (see Graphs 7.1-7.8). While this seems opposite to the standard behavior expected, it is likely due to pupil dilation – if the negative spherical aberration level did not change but the pupil size increased as the accommodative system relaxed, an increase in negative spherical aberration would be found. However, the expected correlation between increased accommodative demand and decreased negative spherical aberration was seen consistently when the accommodative demand was static, in all conditions aside from the flippers.

While a great deal of analysis can be gleaned from the results of this pilot study, there existed limitations in the study design that affected the data collection of each participant in each induction-testing modality to some degree. Data corruption during testing occurred via both involuntary and voluntary actions of the participant in the project set-up.

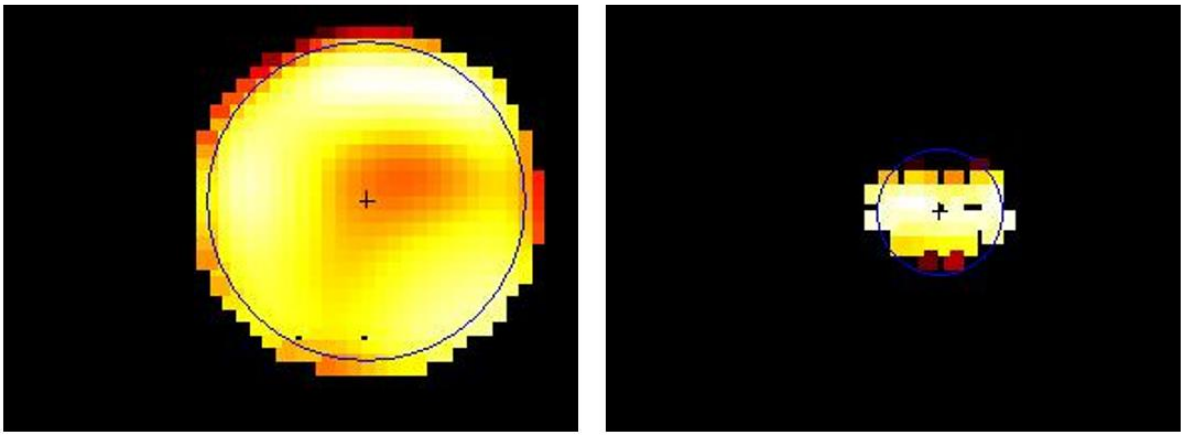
Involuntary data corruption occurred when the COAS image capture did not provide usable data for analysis. This occurred if the participant's eye moved off-center (resulting in the wavefront image moved partially off screen, or Purkinje images which corrupt the center-most

[113] López-Gil M and Fernández-Sánchez V. The change of spherical aberration during accommodation and its effect on the accommodative response. Journal of Vision. 2010 Nov. 10(13):12, 1-15.

part of the image), if the participant were blinking at the time of image capture (resulting in no data), or if the method resulted in a lack of image capture (e.g. if the edge of lens flipper obscured the wavefront image).

Figure 7

Examples of COAS Wavefront Images



Good quality image capture Poor quality image capture

With the COAS wavefront image capture occurring every 2 seconds throughout the duration of the tasks, though many data points were collected for each participant, they were not necessarily measured at the same time during the task. This discrepancy existed between participants as well as between tasks performed by the same participant. Additional variability of data capture time occurred because the COAS system was run through Windows XP, and had a capability of just 43 image captures before it shut down. Mathematically, this converts to a shut down every 1 minute 26 seconds, and was therefore expected to occur 10 times per 15 minute testing condition. When this occurred in this experiment, the investigator would as quickly as possible restart the "free running" alignment screen, confirm and/or adjust the patient's positioning to ensure good quality of wavefront images, and begin acquiring the next set of 43

data points. This process took at least 10 seconds, longer if it were discovered on the "free running" screen that the image capture needed adjusting (e.g. if Purkinje images were visible or the participant was not aligned properly).

Consider the binocular baseline task, performed for a total of 15 minutes across all participants. Theoretically, 450 total image captures were to be collected, if the COAS system were running continuously. Highlighted in Table 22, the variability of data volume collected is clear.

Table 22

Binocular Baseline Data Captured (with highlights indicating data variability)

					Causes of corrupted images		
Participant Number	**Total Images captured**	**Total usable images**	**Total images missing**	**Total corrupted images**	**Blinks**	**Poor image capture**	**Purkinje distortion**
01	387	325	63	62	17	13	32
03	423	393	27	30	19	11	0
05	374	254	76	120	14	100	6
06	412	298	38	114	5	6	103
07	383	299	67	84	36	26	22
08	389	310	61	79	28	37	14
09	371	223	79	148	12	81	55
10	371	328	79	43	18	25	0

In theory, more image capture would be indicative of less fatigue. This could have been an additional measure to compare with the time to fatigue (in seconds) results. However, with the large amount of error in data capture, the image capture variable does not represent a viable analysis of fatigue occurrence.

Similar variability was seen within every task presented to each participant. To limit the variability in data volume and times of data collection between participants and between tasks performed by the same participant, future experiments utilizing the COAS in real-time image capture would benefit from a shorter test duration. Limiting wavefront image captures to the maximum capability of the COAS system would prevent variability of time during testing that the data points were obtained across participants and tasks. Another benefit to eliminating the need to restart the data collection in the middle of a task, is the minimization of total data points collected. Fewer data points could be exported and analyzed quickly for corruption (due to the blinks, poor image capture, or Purkinje images), allowing the investigator to repeat the test, if needed, to improve the data quality.

The second type of data corruption seen in this pilot study was voluntary data corruption, which occurred when participants did not follow the instructions given by the investigator. Examples of this were not malicious in nature – none of the participants were actively disobeying instructions. Rather, errors arose from poor understanding of the task or by nature of a participant's eye to behave differently than expected. This type of corruption arose in three of the four testing scenarios: suppression of an eye during the close working distance condition, and variations of time to flipper change in the monocular and binocular flipper conditions.

Suppression of an eye during the close working distance condition resulted with inaccurate data collection. This occurred most obviously during Participant 08's fourth testing scenario, which allowed completion of the full 15 minutes (900 seconds) of data collection, and an end-rating of just 50% "barely tolerable eyestrain." This data is presented in Table 23.

Table 23

Close Working Distance Time to Fatigue and Subjective Eyestrain Results

Participant	Time to Fatigue (seconds)	Percent "Barely Tolerable Eyestrain" Achieved
1	396	100
3	262	100
5	432	100
6	82	100
7	263	100
8	900	50
9	72	100
10	160	100

Participant 08's 900 seconds of test duration may be contrasted with the next longest time to reach 100% "barely tolerable eyestrain" (Participant 05) at 432 seconds (7 minutes 15 seconds). Excluding Participant 08, the average time to the stopping point of "100% barely tolerable eyestrain" for the close working distance scenario was 254 seconds (4 minutes 14 seconds), clearly indicating that Participant 08's results were an outlier.

Video recording of the binocular and monocular flipper testing scenarios showed how each participant's time to change the binocular and monocular flippers varied. The instructions for the flipper conditions were to clear the stimulus screen and make a Mahjong tile match, before flipping the lens. For example, in both the monocular and binocular flipper conditions, Participant 09 had durations between flips between of as little as 2 seconds both at the beginning and end of the testing session. Participant 05 had similar speed with the binocular flippers. The only possibility of flipping a lens this quickly would be if the participant had memorized more than one tile match in the game, likely when the vision was clearest. This would allow the participant to make matches even if they had not fully cleared the vision of the game board.

Memorizing tile location and planning future matches would allow for faster flipping, and more time spent in the more visually comfortable flipper position. This behavior is in contrast to Participant 06, who, for example, at 229 seconds (the 3 minutes 49 second mark) of the binocular flipper testing, required 18 seconds to remove the -3.00 binocular flipper, and then required a full 69 seconds of time without the flipper in place to focus enough to make a match before replacing the flipper at 316 seconds (the 5 minutes 16 seconds mark). Interestingly, speed between flips seemed to have little consequence on the time until stopping due to "100% barely tolerable eyestrain achieved." Participant 09 (fast flipper) stopped the trial at 137 seconds (2 minutes 17 seconds), Participant 05 (fast flipper) at 430 seconds (7 minutes 10 seconds), and participant 06 (slow flipper), at 353 seconds (5 minutes 53 seconds). Involuntary and voluntary data corruption aside, the future usability of the testing scenarios may be further dissected based on the quality of the data that was collected.

While the binocular and monocular flipper conditions were successful at inducing asthenopia in every participant, the COAS data collected at each phase of the flip and recovery is necessary to provide accurate analysis. Unfortunately, the difficulty of producing adequate wavefront capture resulted in less than optimal data. Table 24 highlights the variability of capture rate.

Table 24

Binocular Flippers Capture Rate (with highlights indicating data variability)

Participant Number	Total Images captured (ideal, based on time)	Total usable images	Testing Duration (min:sec)	Capture Rate (%)
01	302	171	10:04	56.6
03	110	46	3:41	41.8
05	215	37	7:10	17.2
06	176	116	5:53	65.9
07	98	16	3:16	16.3
08	150	52	5:00	34.6
09	68	14	2:17	20.5
10	111	11	3:42	9.9

Considering modifications for future pilot studies also prove to highlight the binocular and monocular flipper task's vulnerabilities. In this study, each participant moved the flippers at a unique pace, while images were captured every 2 seconds (restarts to the COAS system every 1 minute 26 seconds notwithstanding). Therefore, image capture as needed at every phase of the accommodation/recovery spectrum could easily be missed. It may be considered that moving the flipper at a designated rate could force image capture at a specific time, however, this is also expected to fail, as a forced flip may precede the completion of the participant's accommodative recovery, resulting in missing or corrupted data as well. Therefore, while it is true that binocular and monocular flipper tasks are adequate in inducing asthenopia in a participant, it is not an effective task when the goal is of real-time analysis. Measurements taken with these two tasks result with missing and variable data which is not capable of being compared between readings captured with control and test lenses, as future studies anticipate performing.

The close working distance scenario also concluded with poor image capture results, due to the presence of the +5.00 DS spectacles the participants wore for the testing scenario. The COAS had difficulty producing quality wavefront images through the spectacles. Table 25 shows the poor and variable capture rate associated with the close working distance condition.

Table 25

Close Working Distance Capture Rate (with highlights indicating data variability)

Participant Number	Total Images captured (ideal, based on time)	Total usable images	Testing Duration (min:sec)	Capture Rate (%)
01	197	81	6:35	41.1
03	145	74	4:50	51.0
05	217	68	7:15	31.3
06	46	31	1:32	67.4
07	130	28	4:21	21.5
08	450	84	15:00	18.6
09	45	15	1:30	33.3
10	110	26	3:41	23.6

Ultimately, with future research in mind, it was the small font condition that provided the best option for asthenopia induction with accurate COAS wavefront detection. The small font condition resulted with the most accurate paraxial accommodation on the target stimulus across participants, with a consistent amount of spherical aberration. Considerations may be made to the stimulus design itself, which in this pilot study, were designed to mimic small font designs of historical studies.[114,115] The 1 mm sized font on the Mahjong game tiles was found to produce a visually acceptable, though difficult, visual scenario, creating a task which all participants were capable of performing, as they had normal accommodative ability and were sporting an optimal

[114] Sheedy JE, et al. Is All Asthenopia the Same?
[115] Gowrisankaran S, et al. Eyelid Squint Response to Asthenopia-Inducing Conditions.

refractive correction. On average, the time to "100% barely tolerable eyestrain achieved" in the small font condition was 610 seconds (10 minutes 10 seconds). This resulted with an average of 7 cycles per participant of the COAS, with variability introduced each cycle by time lost to restart the system. With less potential variability, the small font condition is the most effective of the testing scenarios presented in this pilot study.

In conclusion, by limiting the duration of testing to the maximum allowed by the COAS in a single cycle, and by eliminating the induction stimulus categories that provided less than optimal wavefront image results, future studies utilizing a variation of the small font stimulus design and optics table set up may provide the data necessary to interpret the onset of asthenopia in real time. This method of measuring accommodation in real-time could then be replicated with control and test contact lenses, such as the Biofinity Sphere and Biofinity Energys contact lenses, respectively, to show if a participant is actively utilizing the add power in the lens designed to reduce ocular fatigue. Results could provide an investigator with a conclusion that the test contact lens was or was not found to objectively reduce the signs of asthenopia as defined by refractive state, pupil size, and spherical aberration. Comparison to subjective data collected would then show if any reduction in asthenopia symptoms was due to the eye's utilization of the unique contact lens optics, or due to the placebo effect.

Conclusions

The results of the pilot testing performed of the methods presented in this thesis provide an important increase in the knowledge of the capabilities and limitations of the COAS aberrometer as it may be used in the investigation of defocus, pupil size, and spherical aberration in real-time testing scenarios. Analysis of the results of the four stimulus items tested revealed that the most promising task stimulus to induce asthenopia while collecting objective data was the small font condition.

The methods outlined in this thesis to provide (1) baseline testing (with testing at optical infinity, and with the Mahjong game stimulus at its optimal working distance and font size), to (2) collect video and audio recording data via the Go-Pro Hero 4 camera (to analyze fissure height, and to accurately measure time to fatigue), to (3) account for possible confounding factors (Medmont corneal topographer use to evaluate non-invasive tear break up time), and to (4) correlate with subjective patient responses (Eye Frequency Rating Questionnaire), provide a process by which future test results may be accurately and thoroughly analyzed.

As the use of digital devices in our daily work, school, and social lives continues to increase, the clinical prevalence of asthenopia will also continue to grow. Increasing our knowledge of the efficacy of treatment options, particularly in the underserved contact lens population, will prove extremely useful.

Appendix 1 – Case Report Forms

0.1 SCREENING VISIT

Date_____ **Study** **Asthenopia Induction** **Participant study ID**_____

ICL Checklist for Prospective Participant (PP)

- ☐ ICL given to PP
- ☐ PP given ample time to read ICL
- ☐ PP given opportunity to ask questions
- ☐ PP, investigator and witness correctly signed and dated ICL
- ☐ PP given copy of ICL
  - ☐ PP declined copy of ICL

History

Age_____ ☐ Female ☐ Male

Current lens type: _____ Typical time of lens insertion: _____ am / pm *(circle)*

Typical time of lens removal: _____ am / pm *(circle)*

Lens wear frequency: Days/week: _____ Current care system: _____

Regular use of rewetting /lubricant drops: ☐ Yes ☐ No

Health History and medications: ☐ Yes ☐ None *If yes, complete 0.2 Medical History Form*

Allergies: ☐ Yes ☐ None *If yes, complete 0.2 Medical History Form*

Other comments: _____

Complete 0.3 Pre-Study Questionnaire ☐ **yes** ☐ **no**

Entrance Snellen VA: OD 20/____

OS 20/____

	OD			OS		
Automated Refraction	Sph (±Diop)	Cyl (-Diop)	Axis (Deg)	Sph (±Diop)	Cyl (-Diop)	Axis (Deg)
	_ . _ _	_ . _ _	_ _ _	_ . _ _	_ . _ _	_ _ _
Automated Keratometry	H (mm)	V (mm)	Cyl (-Diop) / Axis (Deg)	H (mm)	V (mm)	Cyl (-Diop) / Axis (Deg)
	_ . _ _	_ . _ _	_ . _ _ / _ _ _	_ . _ _	_ . _ _	_ . _ _ / _ _ _
Current Spectacle Rx	Sph (±Diop)	Cyl (-Diop)	Axis (Deg)	Sph (±Diop)	Cyl (-Diop)	Axis (Deg)
	_ . _ _	_ . _ _	_ _ _	_ . _ _	_ . _ _	_ _ _
Non-Invasive TBUT (Medmont)	**1.**_____**2.** _____**3.** _____ **Average:** _____			**1.**_____**2.** _____**3.** _____ **Average:** _____		
Interpupillary Distance (mm)	_____					

Complete 0.4 Entrance Biomicroscopy Form ☐ **yes** ☐ **no**

Vision assessment:

	OD				OS			
Dry Subjective Refraction (HCHI) May only add 0.25D more minus for subjective visual improvement.	Sph (±D)	Cyl (-D)	Axis (Deg)	VA (±logM)	Sph (±D)	Cyl (-D)	Axis (Deg)	VA (±logM)
	_ . _ _	_ . _ _	_ _ _	_ . _ _	_ . _ _	_ . _ _	_ _ _	_ . _ _

4M	4M	HI ILLUM/HC					
50	1.0	R	N	O	V	S	
55	0.9	Z	C	R	D	H	
60	0.8	N	V	S	O	K	
65	0.7	D	R	Z	K	O	
70	0.6	S	N	H	C	V	
75	0.5	C	R	V	S	K	
80	0.4	V	K	C	N	H	
85	0.3	S	V	K	D	N	
90	0.2	K	D	H	Z	C	
95	0.1	H	Z	C	O	R	
100	0.0	O	K	D	H	N	
105	-0.1	Z	O	N	K	C	
110	-0.2	R	H	S	V	D	
115	-0.3	D	S	O	R	Z	

4M	4M	HI ILLUM/HC					
50	1.0	C	O	H	Z	V	
55	0.9	S	Z	N	D	C	
60	0.8	V	K	C	N	R	
65	0.7	K	C	R	H	N	
70	0.6	Z	K	D	V	C	
75	0.5	H	V	O	R	K	
80	0.4	R	H	S	O	N	
85	0.3	K	S	V	R	H	
90	0.2	H	N	K	C	D	
95	0.1	N	D	V	K	O	
100	0.0	D	H	O	S	Z	
105	-0.1	V	R	N	D	O	
110	-0.2	C	Z	H	K	S	
115	-0.3	O	R	Z	S	K	

Snellen VA:	**20/**	**20/**
Near Snellen VA (@ 40cm)	**20/**	**20/**

Phoria Testing (Δ @ 4m)	
Phoria Testing (Δ @ 40cm)	
Phoria Testing (Δ @ 40cm w/+1.00D add)	
Gradient Phoria (near - gradient / +1.00)	
Base In Vergence Ranges (Blur/Break/Recovery)	_____ / _____ / _____
Base Out Vergence Ranges (Blur/Break/Recovery)	_____ / _____ / _____

	OD				OS			
Instillation 1% Tropicamide	Time of instillation:_____ Wait 30 minutes before proceeding to wet retinoscopy and refraction. Time of testing restarting: _____							
Wet Retinoscopy (HCHI)	Sph (±D)	Cyl (-D)	Axis (Deg)	VA (±logM)	Sph (±D)	Cyl (-D)	Axis (Deg)	VA (±logM)
	_ . _ _	_ . _ _	_ _ _	_ . _ _	_ . _ _	_ . _ _	_ _ _	_ . _ _
	4M 50 / 1.0	55 / 0.9	60 / 0.8	65 / 0.7	70 / 0.6	75 / 0.5	80 / 0.4	85 / 0.3	90 / 0.2	95 / 0.1	100 / 0.0	105 / -0.1	110 / -0.2	115 / -0.3
	HI ILLUM/HC	R N O V S	Z C R D H	N V S O K	D R Z K O	S N H C V	C R V S K	V K C N H	S V K D N	K D H Z C	H Z C O R	O K D H N	Z O N K C	R H S V D	D S O R Z
Snellen VA:	**20/**				**20/**			
Wet Subjective Refraction (HCHI) May only add 0.25D more minus for subjective visual improvement.	Sph (±D)	Cyl (-D)	Axis (Deg)	VA (±logM)	Sph (±D)	Cyl (-D)	Axis (Deg)	VA (±logM)
	_ . _ _	_ . _ _	_ _ _	_ . _ _	_ . _ _	_ . _ _	_ _ _	_ . _ _
	4M 50 / 1.0	55 / 0.9	60 / 0.8	65 / 0.7	70 / 0.6	75 / 0.5	80 / 0.4	85 / 0.3	90 / 0.2	95 / 0.1	100 / 0.0	105 / -0.1	110 / -0.2	115 / -0.3
	HI ILLUM/HC	R N O V S	Z C R D H	N V S O K	D R Z K O	S N H C V	C R V S K	V K C N H	S V K D N	K D H Z C	H Z C O R	O K D H N	Z O N K C	R H S V D	D S O R Z
Snellen VA:	**20/**				**20/**			

INCLUSION / EXCLUSION CRITERIA

Y	N	INCLUSION	Y	N	EXCLUSION
☐	☐	Oculo-visual examination in the last two years;	☐	☐	Has never worn contact lenses before;
☐	☐	Between 18 and 35 years of age and has full legal capacity to volunteer;	☐	☐	Any systemic disease affecting ocular health;
☐	☐	Has read and understood the informed consent letter;	☐	☐	Is using any systemic or topical medications that will affect ocular health;
☐	☐	Is willing and able to follow instructions and maintain the appointment schedule;	☐	☐	Has any ocular pathology or anomaly that would affect the wearing of the lenses;
☐	☐	Is correctable to a visual acuity of 20/25 or better (in each eye) with their habitual correction or 20/20 best corrected;	☐	☐	Has persistent, clinically significant corneal or conjunctival staining using sodium fluorescein dye;
☐	☐	Currently wears, or has previously successfully worn, soft contact lenses between –0.50 and -6.00D;	☐	☐	Is aphakic;
☐	☐	Spherical Contact Lens Rx between -0.50 and -6.00 and spectacle cylinder ≤ -0.75;	☐	☐	Has anisometropia of ≥2.00;
☐	☐	Has not worn lenses for at least 12 hours before the examination;	☐	☐	Has undergone corneal refractive surgery;
☐	☐	Has a subjective response at baseline, which indicates a history of eye fatigue symptoms of frequency at least once per week.	☐	☐	Has any dry eye symptoms (CLDEQ8≥12)
			☐	☐	Is participating in any other type of eye related clinical or research study.

Based on the study inclusion/exclusion criteria, is the participant suitable for this study? ☐ Yes ☐ No ☐ TBD

Is an additional screening visit required? ☐ Yes ☐ No

Comments: ☐ none

Investigator signature: _____ **Date:** _____

Complete 0.5 Exit Biomicroscopy Form ☐ **yes** ☐ **no**

Exit Snellen VA: OD 20/____ PinHole (if needed) 20/____

OS 20/____ PinHole (if needed) 20/____

0.2 MEDICAL HISTORY FORM

Date_____ **Study** **Asthenopia Induction** **Participant study ID**_____

SCREENING APPOINTMENT

	YES*	NO
Does the participant have any medications to report?	☐	☐
Does the participant have any relevant past and/ or concomitant medical condition, past surgeries, medications to report?	☐	☐
Does the participant have any planned surgeries or trips to the hospital to report?	☐	☐

** If any of the questions has been answered with 'Yes', please complete the relevant sections below*

RELEVANT MEDICAL HISTORY

1. Medical conditions / Surgeries:

Start Date: _____ DD / MM / YYYY OR _____ MM / YYYY

End Date: ☐ Ongoing _____ DD / MM / YYYY OR _____ MM / YYYY

Associated medication: ☐ Entered below OR ☐ None

2. Medical conditions / Surgeries:

Start Date: _____ DD / MM / YYYY OR _____ MM / YYYY

End Date: ☐ Ongoing _____ DD / MM / YYYY OR _____ MM / YYYY

Associated medication: ☐ Entered below OR ☐ None

3. Medical conditions / Surgeries:

Start Date: _____ DD / MM / YYYY OR _____ MM / YYYY

End Date: ☐ Ongoing _____ DD / MM / YYYY OR _____ MM / YYYY

Associated medication: ☐ Entered below OR ☐ None

PRIOR AND CONCOMITANT MEDICATIONS

Medication				
Time Frame	Start Date: _____ DD / MM / YYYY	End Date: _____ DD / MM / YYYY OR ☐ Ongoing		
Administration	Dose:	Unit:	Route:	Frequency:
Indication	Condition: #__			

Medication				
Time Frame	Start Date: _____ DD / MM / YYYY	End Date: _____ DD / MM / YYYY	OR ☐ Ongoing	
Administration	Dose:	Unit:	Route:	Frequency:
Indication	Condition: #__			
Medication				
Time Frame	Start Date: _____ DD / MM / YYYY	End Date: _____ DD / MM / YYYY	OR ☐ Ongoing	
Administration	Dose:	Unit:	Route:	Frequency:
Indication	Condition: #__			
Medication				
Time Frame	Start Date: _____ DD / MM / YYYY	End Date: _____ DD / MM / YYYY	OR ☐ Ongoing	
Administration	Dose:	Unit:	Route:	Frequency:
Indication	Condition: #__			

DOCUMENTATION OF ALLERGIES

Does the participant have a history of allergies to report? ☐ Yes ☐ No

Are there any ocular symptoms associated with the allergies, in general? ☐ Yes ☐ No

Are there currently any ocular symptoms due to allergies to report? ☐ Yes ☐ No

Does the participant usually require medications at the time of active allergies? ☐ Yes ☐ No

If yes, please indicate: ☐ Redness ☐ Itchy eyes ☐ Watering ☐ Sore eyes ☐ Burning

	Drug	Environment	Food	Other
Type of allergy				

Signature: _____ **Initials:** _____ **Date:** _____

0.3 Pre Study Questionnaire

Date_____ **Study** **Asthenopia Induction** **Participant study ID**_____

Eye Fatigue Experiences Questionnaire (@ Baseline, with habitual)

Now we would like to ask you about eye fatigue. Eye fatigue is the physical discomfort of your eyes after spending periods of time throughout the day in front of a digital screen, like a computer or smartphone.

Based on the description above, how often do you experience eye fatigue? (Select one answer.)

Multiple Times Per Day	Once Per Day	A Few Times Per Week	Once Per Week	2-3 Times Per Month	Once Per Month	At Least Once Every 3 Months	Less Often Than Once Every 3 Months	I Never Experience Eye Fatigue
O	O	O	O	O	O	O	O	O

If answered positively to experiencing fatigue (once per week or greater)

1. **On average, after you wake up, how many hours does it take before you feel that your eyes are getting fatigued?** _____
2. **Which of the following symptoms best describe the sensations you experience in association with eye fatigue?**
   a. Put a tick mark next to each sensation that you perceive in relation to digital screen use
   b. THEN. Rank your ***TOP 3 ONLY*** in order of frequency. E.g The most frequent symptom = 1; second most frequent =2; third most frequent = 3
   c. THEN. Rank your ***TOP 3 ONLY*** in order of severity. E.g The most severe symptom = 1; second most severe =2; third most severe = 3
   d. THEN. Rank your ***TOP 3 ONLY*** in order of how bothersome the symptom is. E.g The most bothersome symptom = 1; second most bothersome =2; third most bothersome= 3

Occurs y/n	Rank			Symptom	Occurs y/n	Rank			Symptom
	F	S	B			F	S	B	
				Tiredness					Text coming in and out of focus
				Heaviness around eyes					Losing your place in text
				Pain					Text fading
				Blurred Vision					Itchiness
				Double Vision					Grittiness
				Headache					Dryness
				Sleepy					Watery eyes/Tearing
				Pulling feeling					Soreness
				Text Floating					Glare
				Other (Please state)					

Eye Fatigue Rating Questionnaire (Severity only)

Severity

0□	25□	50□	75□	100□
None	Mild	Moderate	Severe	Extreme

On this scale of 0 to 100 how would you grade the severity of the following symptoms on average with computers or digital devices, with 100 representing extreme/debilitating symptoms and 0 representing no symptoms experienced:

1. Burning _____
2. Tired eyes _____
3. Eye pain _____
4. Eye ache or strain _____
5. Eye irritation _____
6. Tearing/watery eyes _____
7. Blurry or double vision, or a struggle to keep letters or words clear while reading _____
8. Soreness in eyes _____
9. Dryness in eyes _____
10. Headaches _____
11. Words or letters appearing to move or float when reading _____

CLDEQ-8

1. Questions about **EYE DISCOMFORT:**
   a. During a typical day in the past 2 weeks, **how often** did your eyes feel discomfort while wearing your contact lenses?
      0 Never
      1 Rarely
      2 Sometimes
      3 Frequently
      4 Constantly

   b. When your eyes felt discomfort with your contact lenses, **how intense was this feeling of discomfort** at the end of your wearing time?

Never have it	Not at all				Very
have it	Intense				Intense
0	**1**	**2**	**3**	**4**	**5**

2. Questions about **EYE DRYNESS:**
   a. During a typical day in the past 2 weeks, **how often** did your eyes feel dry?
      0 Never
      1 Rarely
      2 Sometimes
      3 Frequently
      4 Constantly

   b. When your eyes felt dry, **how intense was this feeling of dryness** at the end of your wearing time?

Never have it	Not at all				Very
have it	Intense				Intense
0	**1**	**2**	**3**	**4**	**5**

3. Question about **CHANGEABLE, BLURRY VISION:**
   a. During a typical day in the past 2 weeks, **how often** did your vision change between clear and blurry or foggy while wearing your contact lenses?
      0 Never
      1 Rarely
      2 Sometimes
      3 Frequently
      4 Constantly

   b. When your vision was blurry, **how noticeable with the changeable, blurry, or foggy vision** at the end of your wearing time?

Never have it	Not at all				Very
have it	Intense				Intense
0	**1**	**2**	**3**	**4**	**5**

4. Question about **CLOSING YOUR EYES**:
During a typical day in the past 2 weeks, **how often** did your **eyes bother you so much that you wanted to close them**?

0 Never
1 Rarely
2 Sometimes
3 Frequently
4 Constantly

5. Question about **REMOVING YOUR LENSES**:
How often during the past 2 weeks, did your eyes *bother you so much* while wearing your contact lenses that you felt as if you needed to stop whatever you were doing and **take out your contact lenses**?

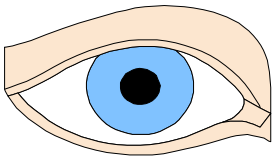
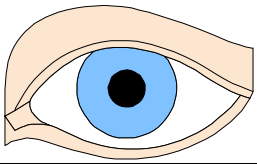
1 Never
2 Less than once a week
3 Weekly
4 Several times a week
5 Daily
6 Several times a day

Score: 1a + 1b + 2a + 2b + 3a + 3b + 4 + 5 = Total

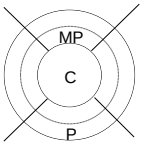
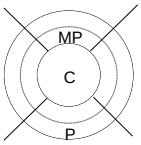
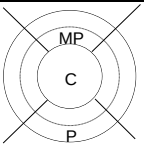
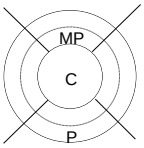
__ + __ + __ + __ + __ + __ + __ + __ = _____

0.4 ENTRANCE BIOMICROSCOPY

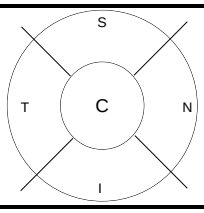
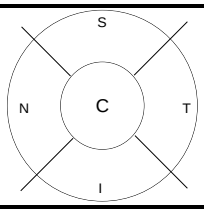
Date_____ **Study** **Asthenopia Induction** **Participant study ID**_____

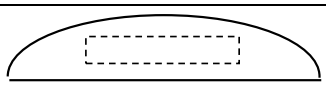
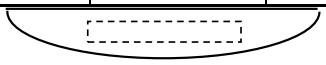
EXTERNALADNEXA ANOMALIES	**OD**	**OS**
Absent: ☐ Describe:_____ _____	. 	

HYPEREMIA			
Bulbar 0-4 (0.25 steps)	0 None 1 Slight injection of conjunctival vessels 2 Mild injection 3 Moderate injection 4 Severe injection	__ . __ __	__ . __ __
Limbal 0-4 (0.25 steps)		__ . __ __	__ . __ __

CORNEA & ANTERIOR EYE		
Scars or other corneal observations:	Absent ☐ Present ☐ & Describe:  _____ _____	Absent ☐ Present ☐ & Describe:  _____ _____
Infiltrates: Size (diameter) of largest infiltrate 0 = none 3 = 1 - 1.5mm 1 = < 0.5mm 4 = >1.5mm 2 = 0.5 - 1mm Depth of largest infiltrate 0 = none 3 = mid stromal 1 = epithelial 4 = deep stromal 2 = sub-epithelial	 Absent ☐ Present ☐ Complete only if present: C # ____ S ____ D ____ MP#____ S____ D ____	 Absent ☐ Present ☐ Complete only if present: C # ____ S ____ D ____ MP#____ S____ D ____

STAINING	**OD**			**OS**		
Corneal Staining **Type, T 0-4 (0.50 steps)** 0 No staining 1 Trace, minimal superficial diffuse staining or stippling, or trace abrasion or foreign body tracks 2 Mild, regional or diffuse punctate staining, or mild abrasion or foreign body tracks 3 Moderate, significant dense coalesced staining, corneal abrasion or foreign body tracks 4 Severe abrasions greater than 2mm diameter, ulcerations, epithelial loss, or full thickness abrasion	**No staining in any zones ☐**			**No staining in any zones ☐**		
		SUPERIOR None ☐ T _. __ E __ D _. __			**SUPERIOR** None ☐ T _. __ E __ D _. __	
Extent, E: 0-4 (1 step) 0 No staining 1 1-15% of area 2 16-30% of area 3 31-45% of area 4 >45% of area	**TEMPORAL** None ☐ T _. __ E __ D _. __	**CENTRAL** None ☐ T _. __ E __ D _. __	**NASAL** None ☐ T _. __ E __ D _. __	**NASAL** None ☐ T _. __ E __ D _. __	**CENTRAL** None ☐ T _. __ E __ D _. __	**TEMPORAL** None ☐ T _. __ E __ D _. __
Depth, D: 0-4 (0.50 steps) 0 No staining 1 Superficial epithelium 2 Deep epithelium, delayed stromal glow 3 Immediate localized stromal glow 4 Immediate diffuse stromal glow, or full thickness abrasion		**INFERIOR** None ☐ T _. __ E __ D _. __			**INFERIOR** None ☐ T _. __ E __ D _. __	

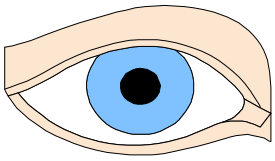
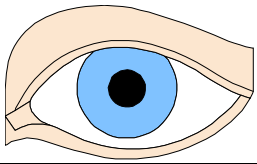
		OD	OS
Optional sketch of staining:			
Causes for Staining		Dehydration Staining: Yes ☐ No ☐ Lens related: Yes ☐ No ☐ Precursor to Seal: Yes ☐ No ☐ SEAL: Yes ☐ No ☐ N/A: ☐	Dehydration Staining: Yes ☐ No ☐ Lens related: Yes ☐ No ☐ Precursor to Seal: Yes ☐ No ☐ SEAL: Yes ☐ No ☐ N/A: ☐
Conjunctival Staining (0-4; 0.5 steps) 0 None 1 Minimal diffuse punctuate 2 Coalescent punctuate 3 Confluent 4 Deep confluent		**No staining in any zones ☐**	**No staining in any zones ☐**
	Nasal	___ . ___	___ . ___
	Temporal	___ . ___	___ . ___
	Superior	___ . ___	___ . ___
	Inferior	___ . ___	___ . ___
Conjunctival Indentation (0-4; 0.5 steps) 0 None 1 Very slight 2 Slight 3 Moderate 4 Severe		**No indentation in any zones ☐**	**No indentation in any zones ☐**
	Nasal	___ . ___	___ . ___
	Temporal	___ . ___	___ . ___
	Superior	___ . ___	___ . ___
	Inferior	___ . ___	___ . ___

Palpebral Conjunctiva		
Hyperemia, H (0-4; 0.25 steps) 0 None 1 Slight injection of conjunctival vessels 2 Mild injection 3 Moderate injection 4 Severe injection **Papillae, P *(Roughness)* (0-4; 0.25 steps)** 0 Uniform satin appearance of conjunctiva 1 Trace, slight loss of smoothness 2 Mild, or scattered papillae/follicles <1mm in diameter 3 Moderate, significant papillae/follicles <1mm in diameter 4 Severe, localised or generalised papillae/ follicles 1mm or more in diameter	 **Upper central area** H __. __ __ P __. __ __  **Lower central area** H __. __ __ P __. __ __	 **Upper central area** H __. __ __ P __. __ __  **Lower central area** H __. __ __ P __. __ __

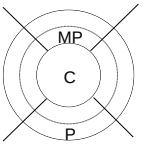
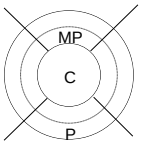
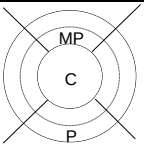
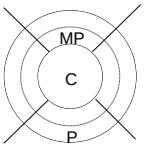
Comments:	None ☐
Signature:	**Date:**

0.5 EXIT BIOMICROSCOPY

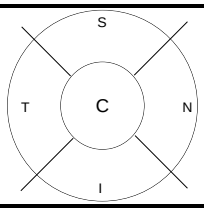
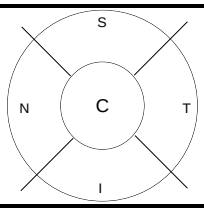
Date_____ **Study** Asthenopia Induction **Participant study ID**_____

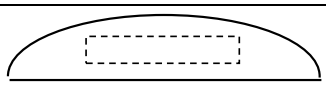
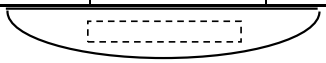
EXTERNALADNEXA ANOMALIES	OD	OS
Absent: ☐ Describe:_____ _____		

HYPEREMIA		OD	OS
Bulbar 0-4 (0.25 steps)	0 None 1 Slight injection of conjunctival vessels 2 Mild injection 3 Moderate injection 4 Severe injection	__ . __ __	__ . __ __
Limbal 0-4 (0.25 steps)		__ . __ __	__ . __ __

CORNEA & ANTERIOR EYE	OD	OS
Scars or other corneal observations:	Absent ☐ Present ☐ & Describe:  _____ _____	Absent ☐ Present ☐ & Describe:  _____ _____
Infiltrates: Size (diameter) of largest infiltrate 0 = none 3 = 1 - 1.5mm 1 = < 0.5mm 4 = >1.5mm 2 = 0.5 - 1mm Depth of largest infiltrate 0 = none 3 = mid stromal 1 = epithelial 4 = deep stromal 2 = sub-epithelial	 Absent ☐ Present ☐ Complete only if present: C # ____ S ____ D ____ MP#____ S____ D ____	 Absent ☐ Present ☐ Complete only if present: C # ____ S ____ D ____ MP#____ S____ D ____

STAINING	OD			OS		
Corneal Staining **Type, T 0-4 (0.50 steps)** 0 No staining 1 Trace, minimal superficial diffuse staining or stippling, or trace abrasion or foreign body tracks 2 Mild, regional or diffuse punctate staining, or mild abrasion or foreign body tracks 3 Moderate, significant dense coalesced staining, corneal abrasion or foreign body tracks 4 Severe abrasions greater than 2mm diameter, ulcerations, epithelial loss, or full thickness abrasion	**No staining in any zones ☐**			**No staining in any zones ☐**		
		SUPERIOR None ☐ T _. __ E __ D _. __			**SUPERIOR** None ☐ T _. __ E __ D _. __	
Extent, E: 0-4 (1 step) 0 No staining 1 1-15% of area 2 16-30% of area 3 31-45% of area 4 >45% of area	**TEMPORAL** None ☐ T _. __ E __ D _. __	**CENTRAL** None ☐ T _. __ E __ D _. __	**NASAL** None ☐ T _. __ E __ D _. __	**NASAL** None ☐ T _. __ E __ D _. __	**CENTRAL** None ☐ T _. __ E __ D _. __	**TEMPORAL** None ☐ T _. __ E __ D _. __
Depth, D: 0-4 (0.50 steps) 0 No staining 1 Superficial epithelium 2 Deep epithelium, delayed stromal glow 3 Immediate localized stromal glow 4 Immediate diffuse stromal glow, or full thickness abrasion		**INFERIOR** None ☐ T _. __ E __ D _. __			**INFERIOR** None ☐ T _. __ E __ D _. __	

		OD	OS
Optional sketch of staining:			
Causes for Staining		Dehydration Staining: Yes ☐ No ☐ Lens related: Yes ☐ No ☐ Precursor to Seal: Yes ☐ No ☐ SEAL: Yes ☐ No ☐ N/A: ☐	Dehydration Staining: Yes ☐ No ☐ Lens related: Yes ☐ No ☐ Precursor to Seal: Yes ☐ No ☐ SEAL: Yes ☐ No ☐ N/A: ☐
Conjunctival Staining (0-4; 0.5 steps) 0 None 1 Minimal diffuse punctuate 2 Coalescent punctuate 3 Confluent 4 Deep confluent		**No staining in any zones ☐**	**No staining in any zones ☐**
	Nasal	___ . ___	___ . ___
	Temporal	___ . ___	___ . ___
	Superior	___ . ___	___ . ___
	Inferior	___ . ___	___ . ___
Conjunctival Indentation (0-4; 0.5 steps) 0 None 1 Very slight 2 Slight 3 Moderate 4 Severe		**No indentation in any zones ☐**	**No indentation in any zones ☐**
	Nasal	___ . ___	___ . ___
	Temporal	___ . ___	___ . ___
	Superior	___ . ___	___ . ___
	Inferior	___ . ___	___ . ___

Palpebral Conjunctiva		
Hyperemia, H (0-4; 0.25 steps) 0 None 1 Slight injection of conjunctival vessels 2 Mild injection 3 Moderate injection 4 Severe injection **Papillae, P *(Roughness)* (0-4; 0.25 steps)** 0 Uniform satin appearance of conjunctiva 1 Trace, slight loss of smoothness 2 Mild, or scattered papillae/follicles <1mm in diameter 3 Moderate, significant papillae/follicles <1mm in diameter 4 Severe, localised or generalised papillae/ follicles 1mm or more in diameter	 **Upper central area** H __. __ __ P __. __ __  **Lower central area** H __. __ __ P __. __ __	 **Upper central area** H __. __ __ P __. __ __  **Lower central area** H __. __ __ P __. __ __

Comments:	None ☐
Signature:	**Date:**

1.1 Asthenopia Induction Trial

Date_____ **Study** **Asthenopia Induction** **Participant study ID**_____

Since the participant's last visit, have they experienced any of the following *(if "Y", describe in space provided):*				
Problems with their eyes or vision?	☐N	☐Y		
Changes to their health?	☐N	☐Y	*If "Y", complete Medical History Form*	
Changes to their concomitant medication(s)?	☐N	☐Y	*If "Y", complete Medical History Form*	
Does the problem/change represent an adverse event?	☐ N/A	☐ N	☐ Y	*If "Y", complete AE Events Forms*

	OD	**OS**
Entrance Snellen VA	**20/**_____	**20/**_____
Non-Invasive TBUT (Medmont)	**1.**_____**2.** _____**3.** _____ **Average:** _____	**1.**_____**2.** _____**3.** _____ **Average:** _____

Does The participant meet the study inclusion criteria? ☐ **yes** ☐ **no**

Complete 1.2 Entrance Biomicroscopy Form ☐ **yes** ☐ **no**

Investigator to insert **Biofinity Sphere** **(Base Curve 8.6, Diameter 14.0)**
(Power empirically calculated according to vertexed cycloplegic refraction) ☐ **yes** ☐ **no**

	OD	**OS**
Lens power (Diop)	_ . _ _	_ . _ _
Lens fit acceptable? *(if "no", participant will discontinue)*	☐ yes ☐ no	☐ yes ☐ no

5min settling period

Vision assessment

	OD		OS	
With CL	**4m**		**40cm**	
HI HCVA (logMAR)	OD	OS	OD	OS
	_ . _ _	_ . _ _	_ . _ _	_ . _ _

HI HCVA (logMAR) 4m

4M	4M	HI ILLUM/HC					
50	1.0	R	N	O	V	S	
55	0.9	Z	C	R	D	H	
60	0.8	N	V	S	O	K	
65	0.7	D	R	Z	K	O	
70	0.6	S	N	H	C	V	
75	0.5	C	R	V	S	K	
80	0.4	V	K	C	N	H	
85	0.3	S	V	K	D	N	
90	0.2	K	D	H	Z	C	
95	0.1	H	Z	C	O	R	
100	0.0	O	K	D	H	N	
105	-0.1	Z	O	N	K	C	
110	-0.2	R	H	S	V	D	
115	-0.3	D	S	O	R	Z	

4M	4M	HI ILLUM/HC					
50	1.0	C	O	H	Z	V	
55	0.9	S	Z	N	D	C	
60	0.8	V	K	C	N	R	
65	0.7	K	C	R	H	N	
70	0.6	Z	K	D	V	C	
75	0.5	H	V	O	R	K	
80	0.4	R	H	S	O	N	
85	0.3	K	S	V	R	H	
90	0.2	H	N	K	C	D	
95	0.1	N	D	V	K	O	
100	0.0	D	H	O	S	Z	
105	-0.1	V	R	N	D	O	
110	-0.2	C	Z	H	K	S	
115	-0.3	O	R	Z	S	K	

HI HCVA (logMAR) 40cm

Near	Hi Illum/HC OD					
1.3	C	O	H	Z	V	
1.2	S	Z	N	D	C	
1.1	V	K	C	N	R	
1	K	C	R	H	N	
0.9	Z	K	D	V	C	
0.8	H	V	O	R	K	
0.7	R	H	S	O	N	
0.6	K	S	V	R	H	
0.5	H	N	K	C	D	
0.4	N	D	V	K	O	
0.3	D	H	O	S	Z	
0.2	V	R	N	D	O	
0.1	C	Z	H	K	S	
0	O	R	Z	S	K	
-0.1	S	C	N	D	Z	
-0.2	N	D	H	K	C	
-0.3	V	K	O	R	H	
LogMAR						

Near	Hi Illum/HC OU					
1.3	Z	R	K	D	C	
1.2	D	N	C	H	V	
1.1	C	D	H	N	R	
1	R	V	Z	O	S	
0.9	O	S	D	V	Z	
0.8	N	O	Z	C	D	
0.7	R	D	N	S	K	
0.6	O	K	S	V	Z	
0.5	K	S	N	H	O	
0.4	H	O	V	S	N	
0.3	V	C	S	Z	H	
0.2	C	Z	D	R	V	
0.1	S	H	R	Z	C	
0	D	N	O	K	R	
-0.1	H	Z	S	C	V	
-0.2	C	K	R	D	Z	
-0.3	R	D	O	N	K	
LogMAR						

	OD	OS
Baseline Non-Invasive TBUT (with CLs) (s) (Medmont)	**1._____2. _____3. _____** **Average: _____**	**1._____2. _____3. _____** **Average: _____**

Participant to complete 1.3 Pre-Testing Subjective Questionnaire ☐ yes ☐ no

Distance Baseline Measures: **☐ yes ☐ no**
(1 minute of viewing target at optical infinity)

Baseline Measures:
(15 minutes of sitting in study configuration: iPhone positioned @ 40cm)

Post-Test: Non-Invasive TBUT (s) (Medmont)	**1._____2. _____3. _____** **Average: _____**	**1._____2. _____3. _____** **Average: _____**

Participant to complete 1.4 Asthenopia Induction Technique 1 ☐ yes ☐ no

Participant to complete 1.5 Asthenopia Induction Technique 2 ☐ yes ☐ no

Participant to complete 1.6 Asthenopia Induction Technique 3 ☐ yes ☐ no

Post-Testing Measures:
(15 minutes of sitting in study configuration: iPhone positioned @ 40cm)

Post-Test: Non-Invasive TBUT (s) (Medmont)	**1._____2. _____3. _____** **Average: _____**	**1._____2. _____3. _____** **Average: _____**

Participant to complete 1.7 Post-Testing Subjective Questionnaire ☐ yes ☐ no

Investigator to remove and discard lenses ☐ yes ☐ no

Complete 1.8 Exit Biomicroscopy Form ☐ yes ☐ no

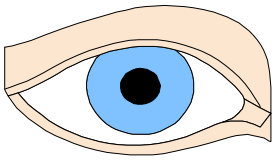
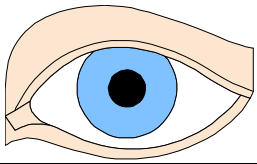
Exit Snellen VA: OD 20/____
OS 20/____

Were any adverse events observed during the study visit? ☐ yes ☐ no If "yes", complete AE Event Form

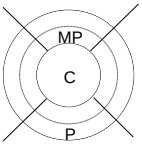
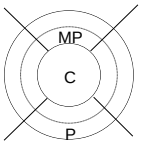
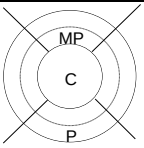
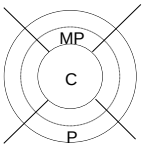
Is the participant eligible to continue in the study? ☐ yes ☐ no ☐ TBD
If N, please describe reason(s) and indicate if discontinued:
Investigator signature: _____
Date:_____

1.2 ENTRANCE BIOMICROSCOPY

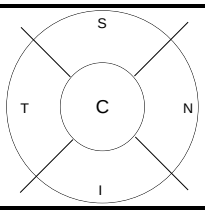
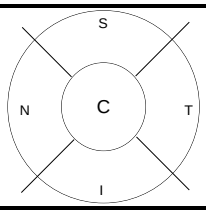
Date_____ **Study** Asthenopia Induction **Participant study ID**_____

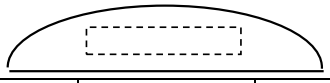
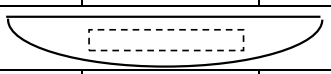
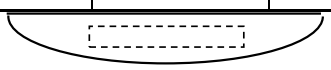
EXTERNALADNEXA ANOMALIES	OD	OS
Absent: ☐ Describe:_____ _____		

HYPEREMIA		OD	OS
Bulbar 0-4 (0.25 steps)	0 None 1 Slight injection of conjunctival vessels 2 Mild injection 3 Moderate injection 4 Severe injection	__ . __ __	__ . __ __
Limbal 0-4 (0.25 steps)		__ . __ __	__ . __ __

CORNEA & ANTERIOR EYE	OD	OS
Scars or other corneal observations:	Absent ☐ Present ☐ & Describe:  _____ _____	Absent ☐ Present ☐ & Describe:  _____ _____
Infiltrates: Size (diameter) of largest infiltrate 0 = none 3 = 1 - 1.5mm 1 = < 0.5mm 4 = >1.5mm 2 = 0.5 - 1mm Depth of largest infiltrate 0 = none 3 = mid stromal 1 = epithelial 4 = deep stromal 2 = sub-epithelial	 Absent ☐ Present ☐ Complete only if present: C # ____ S ____ D ____ MP#____ S____ D ____	 Absent ☐ Present ☐ Complete only if present: C # ____ S ____ D ____ MP#____ S____ D ____

STAINING		OD			OS		
Corneal Staining **Type, T 0-4 (0.50 steps)** 0 No staining 1 Trace, minimal superficial diffuse staining or stippling, or trace abrasion or foreign body tracks 2 Mild, regional or diffuse punctate staining, or mild abrasion or foreign body tracks 3 Moderate, significant dense coalesced staining, corneal abrasion or foreign body tracks 4 Severe abrasions greater than 2mm diameter, ulcerations, epithelial loss, or full thickness abrasion		**No staining in any zones ☐**			**No staining in any zones ☐**		
			SUPERIOR None ☐ T _. __ E __ D _. __			**SUPERIOR** None ☐ T _. __ E __ D _. __	
Extent, E: 0-4 (1 step) 0 No staining 1 1-15% of area 2 16-30% of area 3 31-45% of area 4 >45% of area	**TEMPORAL** None ☐ T _. __ E __ D _. __	**CENTRAL** None ☐ T _. __ E __ D _. __	**NASAL** None ☐ T _. __ E __ D _. __	**NASAL** None ☐ T _. __ E __ D _. __	**CENTRAL** None ☐ T _. __ E __ D _. __	**TEMPORAL** None ☐ T _. __ E __ D _. __
Depth, D: 0-4 (0.50 steps) 0 No staining 1 Superficial epithelium 2 Deep epithelium, delayed stromal glow 3 Immediate localized stromal glow 4 Immediate diffuse stromal glow, or full thickness abrasion		**INFERIOR** None ☐ T _. __ E __ D _. __			**INFERIOR** None ☐ T _. __ E __ D _. __		

		OD	OS
Optional sketch of staining:			
Causes for Staining		Dehydration Staining: Yes ☐ No ☐ Lens related: Yes ☐ No ☐ Precursor to Seal: Yes ☐ No ☐ SEAL: Yes ☐ No ☐ N/A: ☐	Dehydration Staining: Yes ☐ No ☐ Lens related: Yes ☐ No ☐ Precursor to Seal: Yes ☐ No ☐ SEAL: Yes ☐ No ☐ N/A: ☐
Conjunctival Staining (0-4; 0.5 steps) 0 None 1 Minimal diffuse punctuate 2 Coalescent punctuate 3 Confluent 4 Deep confluent		**No staining in any zones ☐**	**No staining in any zones ☐**
	Nasal	___ . ___	___ . ___
	Temporal	___ . ___	___ . ___
	Superior	___ . ___	___ . ___
	Inferior	___ . ___	___ . ___
Conjunctival Indentation (0-4; 0.5 steps) 0 None 1 Very slight 2 Slight 3 Moderate 4 Severe		**No indentation in any zones ☐**	**No indentation in any zones ☐**
	Nasal	___ . ___	___ . ___
	Temporal	___ . ___	___ . ___
	Superior	___ . ___	___ . ___
	Inferior	___ . ___	___ . ___

Palpebral Conjunctiva		
Hyperemia, H (0-4; 0.25 steps) 0 None 1 Slight injection of conjunctival vessels 2 Mild injection 3 Moderate injection 4 Severe injection **Papillae, P *(Roughness)* (0-4; 0.25 steps)** 0 Uniform satin appearance of conjunctiva 1 Trace, slight loss of smoothness 2 Mild, or scattered papillae/follicles <1mm in diameter 3 Moderate, significant papillae/follicles <1mm in diameter 4 Severe, localised or generalised papillae/ follicles 1mm or more in diameter	 **Upper central area** H __. __ __ P __. __ __  **Lower central area** H __. __ __ P __. __ __	 **Upper central area** H __. __ __ P __. __ __  **Lower central area** H __. __ __ P __. __ __

Comments:	None ☐
Signature:	**Date:**

1.3 Pre-Testing Subjective Questionnaire – Asthenopia Induction Trial

Date_____ **Study** **Asthenopia Induction** **Participant study ID**_____

Pre-Testing - Eye Fatigue Rating Questionnaire (Severity only)
Participant is to answer questions based on "overall" or "average" daily symptoms.

Severity

0□	25□	50□	75□	100□
None	Mild	Moderate	Severe	Extreme

On a scale of 0 to 100 how would you grade the severity of the following symptoms on average with computers or digital devices, with 100 representing extreme/debilitating symptoms and 0 representing no symptoms experienced:

1. Burning _____
2. Tired eyes _____
3. Eye pain _____
4. Eye ache or strain _____
5. Eye irritation _____
6. Tearing/watery eyes _____
7. Blurry or double vision, or a struggle to keep letters or words clear while reading _____
8. Soreness in eyes _____
9. Dryness in eyes _____
10. Headaches _____
11. Words or letters appearing to move or float when reading _____

1.4 Induction Trial 1

Date_____ **Study** **Asthenopia Induction** **Participant study ID**_____

Induction Technique (Randomized)
(Circle) **Close WD** **Flippers** **Small Font**

Measurements to be taken prior to technique:

	OD	**OS**
Investigator Lens Surface Rating		
Pre-Test: Non-Invasive TBUT (s) (Medmont)	**1.**_____**2.** _____**3.** _____ **Average:** _____	**1.**_____**2.** _____**3.** _____ **Average:** _____

Eye Fatigue Rating Questionnaire: Severity after Baseline Testing

0□	25□	50□	75□	100□
None	Mild	Moderate	Severe	Extreme

On a scale of 0 to 100 how would you grade the **severity of the following symptoms after the Baseline Testing**, with 100 representing extreme/debilitating symptoms and 0 representing no symptoms experienced:

1. Burning _____
2. Tired eyes _____
3. Eye pain _____
4. Eye ache or strain _____
5. Eye irritation _____
6. Tearing/watery eyes _____
7. Blurry or double vision, or a struggle to keep letters or words clear while reading _____
8. Soreness in eyes _____
9. Dryness in eyes _____
10. Headaches _____
11. Words or letters appearing to move or float when reading _____

Begin Induction Technique; start 15 minute countdown timer.

Time participant stops playing game: _____ **(max 15 minutes)**

If 15 minutes is reached:
Percent of "Barely Tolerable Eyestrain" achieved after 15 minutes of testing:

0	25	50	75	100
No discomfort experienced				Unable to continue task due to discomfort

Game Scores:

Total Number of Stars Achieved:_____

Time to Complete Puzzles: (Note any incomplete puzzles)

Puzzle 1:	Puzzle 8:	Puzzle 15:
Puzzle 2:	Puzzle 9:	Puzzle 16:
Puzzle 3:	Puzzle 10:	Puzzle 17:
Puzzle 4:	Puzzle 11:	Puzzle 18:
Puzzle 5:	Puzzle 12:	Puzzle 19:
Puzzle 6:	Puzzle 13:	Puzzle 20:
Puzzle 7:	Puzzle 14:	Puzzle 21:

Post-Test: Non-Invasive TBUT (s) (Medmont)	**1.**_____**2.** _____**3.** _____ **Average:** _____	**1.**_____**2.** _____**3.** _____ **Average:** _____

15 minute break for rest and post-induction questionnaire.

Eye Fatigue Rating Questionnaire: Severity after Induction Test 1

0□	25□	50□	75□	100□
None	Mild	Moderate	Severe	Extreme

On a scale of 0 to 100 how would you grade the **severity of the following symptoms during the last testing period**, with 100 representing extreme/debilitating symptoms and 0 representing no symptoms experienced:

1. Burning _____
2. Tired eyes _____
3. Eye pain _____
4. Eye ache or strain _____
5. Eye irritation _____
6. Tearing/watery eyes _____
7. Blurry or double vision, or a struggle to keep letters or words clear while reading _____
8. Soreness in eyes _____
9. Dryness in eyes _____
10. Headaches _____
11. Words or letters appearing to move or float when reading _____

1.5 Induction Trial 2

Date_____ **Study** **Asthenopia Induction** **Participant study ID**_____

Induction Technique (Randomized)
(Circle) **Close WD** **Flippers** **Small Font**

Measurements to be taken prior to technique:

	OD	**OS**
Investigator Lens Surface Rating		
Pre-Test: Non-Invasive TBUT (s) (Medmont)	**1.**_____**2.** _____**3.** _____ **Average:** _____	**1.**_____**2.** _____**3.** _____ **Average:** _____

Eye Fatigue Rating Questionnaire: Severity before beginning Induction Test 2

0□	25□	50□	75□	100□
None	Mild	Moderate	Severe	Extreme

On a scale of 0 to 100 how would you grade the **severity of the following symptoms right now**, with 100 representing extreme/debilitating symptoms and 0 representing no symptoms experienced:

1. Burning _____
2. Tired eyes _____
3. Eye pain _____
4. Eye ache or strain _____
5. Eye irritation _____
6. Tearing/watery eyes _____
7. Blurry or double vision, or a struggle to keep letters or words clear while reading _____
8. Soreness in eyes _____
9. Dryness in eyes _____
10. Headaches _____
11. Words or letters appearing to move or float when reading _____

Begin Induction Technique; start 15 minute countdown timer..

Time participant stops playing game: _____ **(max 15 minutes)**

If 15 minutes is reached:
Percent of "Barely Tolerable Eyestrain" achieved after 15 minutes of testing:

0	25	50	75	100
No discomfort experienced				Unable to continue task due to discomfort

Game Scores:

Total Number of Stars Achieved:_____

Time to Complete Puzzles: (Note any incomplete puzzles)

Puzzle 1:	Puzzle 8:	Puzzle 15:
Puzzle 2:	Puzzle 9:	Puzzle 16:
Puzzle 3:	Puzzle 10:	Puzzle 17:
Puzzle 4:	Puzzle 11:	Puzzle 18:
Puzzle 5:	Puzzle 12:	Puzzle 19:
Puzzle 6:	Puzzle 13:	Puzzle 20:
Puzzle 7:	Puzzle 14:	Puzzle 21:

Post-Test: Non-Invasive TBUT (s) (Medmont)	**1.**_____**2.** _____**3.** _____ **Average:** _____	**1.**_____**2.** _____**3.** _____ **Average:** _____

15 minute break for rest and post-induction questionnaire.

Eye Fatigue Rating Questionnaire: Severity after Induction Test 2

0□	25□	50□	75□	100□
None	Mild	Moderate	Severe	Extreme

On a scale of 0 to 100 how would you grade the **severity of the following symptoms during the last testing period**, with 100 representing extreme/debilitating symptoms and 0 representing no symptoms experienced:

1. Burning _____
2. Tired eyes _____
3. Eye pain _____
4. Eye ache or strain _____
5. Eye irritation _____
6. Tearing/watery eyes _____
7. Blurry or double vision, or a struggle to keep letters or words clear while reading _____
8. Soreness in eyes _____
9. Dryness in eyes _____
10. Headaches _____
11. Words or letters appearing to move or float when reading _____

1.6 Induction Trial 3

Date_____ **Study** **Asthenopia Induction** **Participant study ID**_____

Induction Technique (Randomized)
(Circle) **Close WD** **Flippers** **Small Font**

Measurements to be taken prior to technique:

	OD	**OS**
Investigator Lens Surface Rating		
Pre-Test: Non-Invasive TBUT (s) (Medmont)	**1.**_____**2.** _____**3.** _____ **Average:** _____	**1.**_____**2.** _____**3.** _____ **Average:** _____

Eye Fatigue Rating Questionnaire: Severity before beginning Induction Test 3

0□	25□	50□	75□	100□
None	Mild	Moderate	Severe	Extreme

On a scale of 0 to 100 how would you grade the **severity of the following symptoms right now**, with 100 representing extreme/debilitating symptoms and 0 representing no symptoms experienced:

1. Burning _____
2. Tired eyes _____
3. Eye pain _____
4. Eye ache or strain _____
5. Eye irritation _____
6. Tearing/watery eyes _____
7. Blurry or double vision, or a struggle to keep letters or words clear while reading _____
8. Soreness in eyes _____
9. Dryness in eyes _____
10. Headaches _____
11. Words or letters appearing to move or float when reading _____

Begin Induction Technique; start 15 minute countdown timer..

Time participant stops playing game: _____ **(max 15 minutes)**

If 15 minutes is reached:
Percent of "Barely Tolerable Eyestrain" achieved after 15 minutes of testing:

0	25	50	75	100
No discomfort experienced				Unable to continue task due to discomfort

Game Scores:

Total Number of Stars Achieved:_____

Time to Complete Puzzles: (Note any incomplete puzzles)

Puzzle 1:	Puzzle 8:	Puzzle 15:
Puzzle 2:	Puzzle 9:	Puzzle 16:
Puzzle 3:	Puzzle 10:	Puzzle 17:
Puzzle 4:	Puzzle 11:	Puzzle 18:
Puzzle 5:	Puzzle 12:	Puzzle 19:
Puzzle 6:	Puzzle 13:	Puzzle 20:
Puzzle 7:	Puzzle 14:	Puzzle 21:

Post-Test: Non-Invasive TBUT (s) (Medmont)	**1.**_____**2.** _____**3.** _____ **Average:** _____	**1.**_____**2.** _____**3.** _____ **Average:** _____

15 minute break for rest and post-induction questionnaire.

Eye Fatigue Rating Questionnaire: Severity during Induction Test 3

0□	25□	50□	75□	100□
None	Mild	Moderate	Severe	Extreme

On a scale of 0 to 100 how would you grade the **severity of the following symptoms during the last testing period**, with 100 representing extreme/debilitating symptoms and 0 representing no symptoms experienced:

1. Burning _____
2. Tired eyes _____
3. Eye pain _____
4. Eye ache or strain _____
5. Eye irritation _____
6. Tearing/watery eyes _____
7. Blurry or double vision, or a struggle to keep letters or words clear while reading _____
8. Soreness in eyes _____
9. Dryness in eyes _____
10. Headaches _____
11. Words or letters appearing to move or float when reading _____

1.7 Post-Testing Subjective Questionnaire – Asthenopia Induction Trial

Date_____ **Study** **Asthenopia Induction** **Participant study ID**_____

Pre-Testing - Eye Fatigue Rating Questionnaire (Severity only)
Participant is to answer questions based on current symptoms after today's testing.

Severity

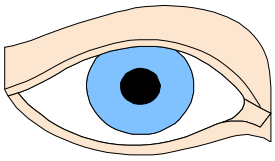
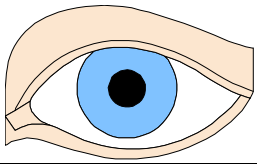
0□	25□	50□	75□	100□
None	Mild	Moderate	Severe	Extreme

On a scale of 0 to 100 how would you grade the severity of the following symptoms after all of today's testing, with 100 representing extreme/debilitating symptoms and 0 representing no symptoms experienced:

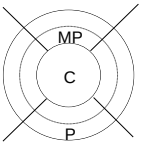
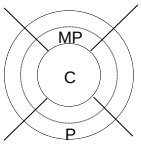
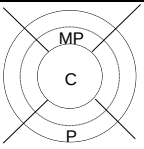
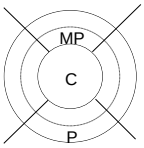
1. Burning _____
2. Tired eyes _____
3. Eye pain _____
4. Eye ache or strain _____
5. Eye irritation _____
6. Tearing/watery eyes _____
7. Blurry or double vision, or a struggle to keep letters or words clear while reading _____
8. Soreness in eyes _____
9. Dryness in eyes _____
10. Headaches _____
11. Words or letters appearing to move or float when reading _____

1.8 EXIT BIOMICROSCOPY

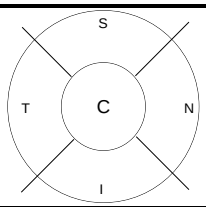
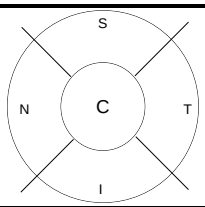
Date_____ **Study** **Asthenopia Induction** **Participant study ID**_____

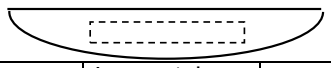
EXTERNALADNEXA ANOMALIES	**OD**	**OS**
Absent: ☐ Describe:_____ _____	. 	

HYPEREMIA			
Bulbar 0-4 (0.25 steps)	0 None 1 Slight injection of conjunctival vessels 2 Mild injection 3 Moderate injection 4 Severe injection	__ . __ __	__ . __ __
Limbal 0-4 (0.25 steps)		__ . __ __	__ . __ __

CORNEA & ANTERIOR EYE		
Scars or other corneal observations:	Absent ☐ Present ☐ & Describe:  _____ _____	Absent ☐ Present ☐ & Describe:  _____ _____
Infiltrates: Size (diameter) of largest infiltrate 0 = none 3 = 1 - 1.5mm 1 = < 0.5mm 4 = >1.5mm 2 = 0.5 - 1mm Depth of largest infiltrate 0 = none 3 = mid stromal 1 = epithelial 4 = deep stromal 2 = sub-epithelial	 Absent ☐ Present ☐ Complete only if present: C # ____ S ____ D ____ MP#____ S____ D ____	 Absent ☐ Present ☐ Complete only if present: C # ____ S ____ D ____ MP#____ S____ D ____

STAINING	**OD**			**OS**		
Corneal Staining **Type, T 0-4 (0.50 steps)** 0 No staining 1 Trace, minimal superficial diffuse staining or stippling, or trace abrasion or foreign body tracks 2 Mild, regional or diffuse punctate staining, or mild abrasion or foreign body tracks 3 Moderate, significant dense coalesced staining, corneal abrasion or foreign body tracks 4 Severe abrasions greater than 2mm diameter, ulcerations, epithelial loss, or full thickness abrasion	**No staining in any zones ☐**			**No staining in any zones ☐**		
		SUPERIOR None ☐ T _. __ E __ D _. __			**SUPERIOR** None ☐ T _. __ E __ D _. __	
Extent, E: 0-4 (1 step) 0 No staining 1 1-15% of area 2 16-30% of area 3 31-45% of area 4 >45% of area	**TEMPORAL** None ☐ T _. __ E __ D _. __	**CENTRAL** None ☐ T _. __ E __ D _. __	**NASAL** None ☐ T _. __ E __ D _. __	**NASAL** None ☐ T _. __ E __ D _. __	**CENTRAL** None ☐ T _. __ E __ D _. __	**TEMPORAL** None ☐ T _. __ E __ D _. __
Depth, D: 0-4 (0.50 steps) 0 No staining 1 Superficial epithelium 2 Deep epithelium, delayed stromal glow 3 Immediate localized stromal glow 4 Immediate diffuse stromal glow, or full thickness abrasion		**INFERIOR** None ☐ T _. __ E __ D _. __			**INFERIOR** None ☐ T _. __ E __ D _. __	

		OD	OS
Optional sketch of staining:			
Causes for Staining		Dehydration Staining: Yes ☐ No ☐ Lens related: Yes ☐ No ☐ Precursor to Seal: Yes ☐ No ☐ SEAL: Yes ☐ No ☐ N/A: ☐	Dehydration Staining: Yes ☐ No ☐ Lens related: Yes ☐ No ☐ Precursor to Seal: Yes ☐ No ☐ SEAL: Yes ☐ No ☐ N/A: ☐
Conjunctival Staining (0-4; 0.5 steps) 0 None 1 Minimal diffuse punctuate 2 Coalescent punctuate 3 Confluent 4 Deep confluent		**No staining in any zones ☐**	**No staining in any zones ☐**
	Nasal	___ . ___	___ . ___
	Temporal	___ . ___	___ . ___
	Superior	___ . ___	___ . ___
	Inferior	___ . ___	___ . ___
Conjunctival Indentation (0-4; 0.5 steps) 0 None 1 Very slight 2 Slight 3 Moderate 4 Severe		**No indentation in any zones ☐**	**No indentation in any zones ☐**
	Nasal	___ . ___	___ . ___
	Temporal	___ . ___	___ . ___
	Superior	___ . ___	___ . ___
	Inferior	___ . ___	___ . ___

Palpebral Conjunctiva		
Hyperemia, H (0-4; 0.25 steps) 0 None 1 Slight injection of conjunctival vessels 2 Mild injection 3 Moderate injection 4 Severe injection **Papillae, P *(Roughness)* (0-4; 0.25 steps)** 0 Uniform satin appearance of conjunctiva 1 Trace, slight loss of smoothness 2 Mild, or scattered papillae/follicles <1mm in diameter 3 Moderate, significant papillae/follicles <1mm in diameter 4 Severe, localised or generalised papillae/ follicles 1mm or more in diameter	 **Upper central area** H __. __ __ P __. __ __  **Lower central area** H __. __ __ P __. __ __	 **Upper central area** H __. __ __ P __. __ __  **Lower central area** H __. __ __ P __. __ __

Comments:	None ☐
Signature:	**Date:**

Appendix 2 - Questionnaires

Eye Fatigue Experiences Questionnaire (@ Baseline, with habitual)

Now we would like to ask you about eye fatigue. Eye fatigue is the physical discomfort of your eyes after spending periods of time throughout the day in front of a digital screen, like a computer or smartphone.

Based on the description above, how often do you experience eye fatigue? (Select one answer.)

Multiple Times Per Day	Once Per Day	A Few Times Per Week	Once Per Week	2-3 Times Per Month	Once Per Month	At Least Once Every 3 Months	Less Often Than Once Every 3 Months	I Never Experience Eye Fatigue
O	O	O	O	O	O	O	O	O

If answered positively to experiencing fatigue (once per week or greater)

1. **On average, after you wake up, how many hours does it take before you feel that your eyes are getting fatigued?** _____
2. **Which of the following symptoms best describe the sensations you experience in association with eye fatigue?**
   a. Put a tick mark next to each sensation that you perceive in relation to digital screen use
   b. THEN. Rank your ***TOP 3 ONLY*** in order of frequency. E.g The most frequent symptom = 1; second most frequent =2; third most frequent = 3
   c. THEN. Rank your ***TOP 3 ONLY*** in order of severity. E.g The most severe symptom = 1; second most severe =2; third most severe = 3
   d. THEN. Rank your ***TOP 3 ONLY*** in order of how bothersome the symptom is. E.g The most bothersome symptom = 1; second most bothersome =2; third most bothersome= 3

Occurs y/n	Rank			Symptom	Occurs y/n	Rank			Symptom
	F	S	B			F	S	B	
				Tiredness					Text coming in and out of focus
				Heaviness around eyes					Losing your place in text
				Pain					Text fading
				Blurred Vision					Itchiness
				Double Vision					Grittiness
				Headache					Dryness
				Sleepy					Watery eyes/Tearing
				Pulling feeling					Soreness
				Text Floating					Glare
				Other (Please state)					

Eye Fatigue Rating Questionnaire (Severity only) - EFRQ

Severity

0□	25□	50□	75□	100□
None	Mild	Moderate	Severe	Extreme

On this scale of 0 to 100 how would you grade the severity of the following symptoms on average with computers or digital devices, with 100 representing extreme/debilitating symptoms and 0 representing no symptoms experienced:

1. Burning _____
2. Tired eyes _____
3. Eye pain _____
4. Eye ache or strain _____
5. Eye irritation _____
6. Tearing/watery eyes _____
7. Blurry or double vision, or a struggle to keep letters or words clear while reading _____
8. Soreness in eyes _____
9. Dryness in eyes _____
10. Headaches _____
11. Words or letters appearing to move or float when reading _____

CLDEQ-8

1. Questions about **EYE DISCOMFORT:**
   - **a.** During a typical day in the past 2 weeks, **how often** did your eyes feel discomfort while wearing your contact lenses?
     - **0** Never
     - **1** Rarely
     - **2** Sometimes
     - **3** Frequently
     - **4** Constantly
   - **b.** When your eyes felt discomfort with your contact lenses, **how intense was this feeling of discomfort** at the end of your wearing time?

Never have it	Not at all				Very
have it	Intense				Intense
0	**1**	**2**	**3**	**4**	**5**

2. Questions about **EYE DRYNESS:**
   - **a.** During a typical day in the past 2 weeks, **how often** did your eyes feel dry?
     - **0** Never
     - **1** Rarely
     - **2** Sometimes
     - **3** Frequently
     - **4** Constantly
   - **b.** When your eyes felt dry, **how intense was this feeling of dryness** at the end of your wearing time?

Never have it	Not at all				Very
have it	Intense				Intense
0	**1**	**2**	**3**	**4**	**5**

3. Question about **CHANGEABLE, BLURRY VISION:**
   - **a.** During a typical day in the past 2 weeks, **how often** did your vision change between clear and blurry or foggy while wearing your contact lenses?
     - **0** Never
     - **1** Rarely
     - **2** Sometimes
     - **3** Frequently
     - **4** Constantly

b. When your vision was blurry, **how noticeable with the changeable, blurry, or foggy vision** at the end of your wearing time?

Never have it	Not at all				Very
have it	Intense				Intense
0	**1**	**2**	**3**	**4**	**5**

4. Question about **CLOSING YOUR EYES**:
During a typical day in the past 2 weeks, **how often** did your **eyes bother you so much that you wanted to close them**?

0 Never
1 Rarely
2 Sometimes
3 Frequently
4 Constantly

5. Question about **REMOVING YOUR LENSES**:
How often during the past 2 weeks, did your eyes *bother you so much* while wearing your contact lenses that you felt as if you needed to stop whatever you were doing and **take out your contact lenses**?

1 Never
2 Less than once a week
3 Weekly
4 Several times a week
5 Daily
6 Several times a day

Score: 1a + 1b + 2a + 2b + 3a + 3b + 4 + 5 = Total

__ + __ + __ + __ + __ + __ + __ + __ = _____

Survey Question Asked if 15 Minutes of Withstanding Asthenopia Induction Technique was Achieved

Percent of “Barely Tolerable Eyestrain” achieved after 15 minutes of testing:

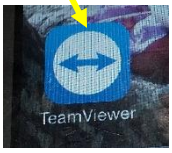
0	25	50	75	100
No discomfort experienced				Unable to continue task due to discomfort

Appendix 3 – Operating Procedures for Testing Stimulus

(1) Standard Operating Procedures for Connecting MacBook and iPhone via TeamViewer

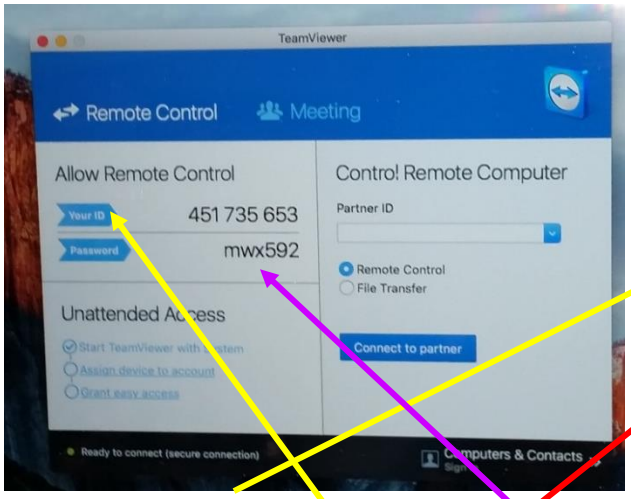
1. Open TeamViewer on the MacBook Pro

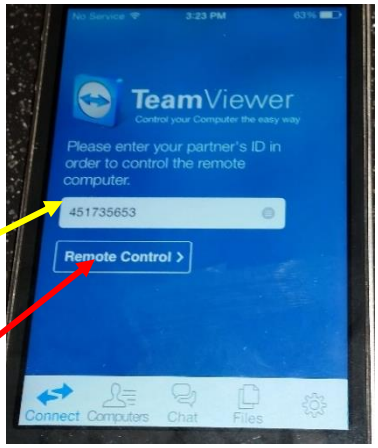
2. Open TeamViewer on the iPhone



These screens will open:

MacBook Pro **iPhone**





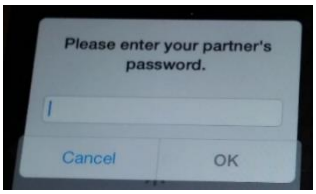
3. This ID number should populate automatically.

   If not, type in the "Your ID" number presented on the computer screen.

4. Press "Remote Control"

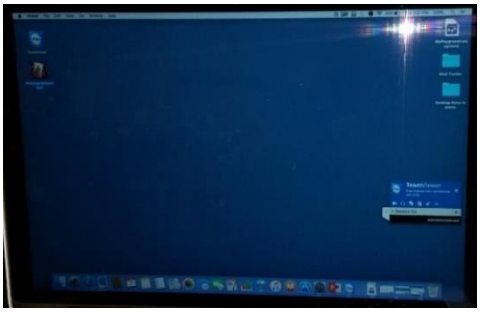
5. The iPhone screen will prompt you to enter the Password.

   Note that this Password may change with each login session.



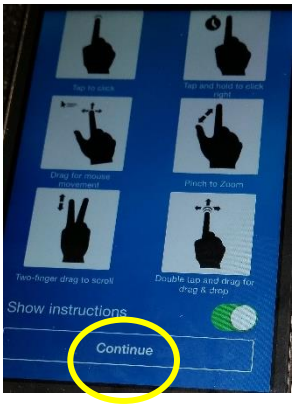
6. The screens on both the MacBook Pro and iPhone will change.

MacBook **iPhone**



Note: This instructions screen may show up on the iPhone.

Click Continue.



Next, rotate the iPhone screen to full screen:

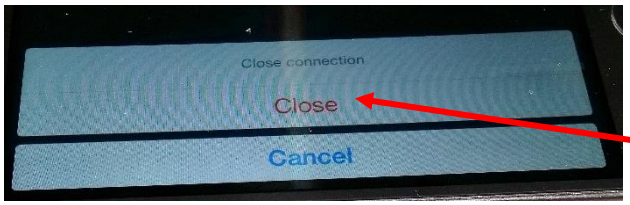
7. Move the Cursor on the iPhone Touchscreen to the far right of the screen, where it is out of the way. This is the LAST touch you make on the iPhone until you want to disconnect.
8. Open Mahjong Solitaire Epic on the MacBook Pro Desktop. Follow the instructions on the Standard Operating Procedures for Mahjong Game (below) for running the game.

9. The participant will be viewing the iPhone screen, while controlling the game with the Apple Magic TrackPad (wirelessly connected to the MacBook Pro, and functioning as a mouse).
10. To Disconnect:

    Click on the keyboard icon in the lower right corner to reveal the TeamViewer setting options.

    To Exit, press the X.

    This screen will show:



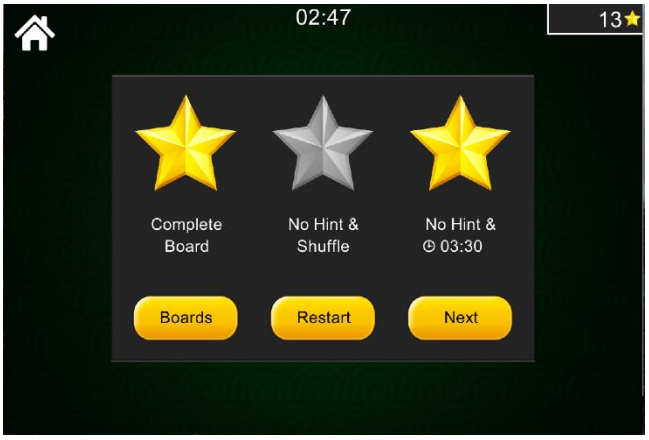
    Select Close.

11. Lastly, a Pop Up with “Sponsored session” will appear on both the MacBook and iPhone. Simply click OK to make the screens disappear.

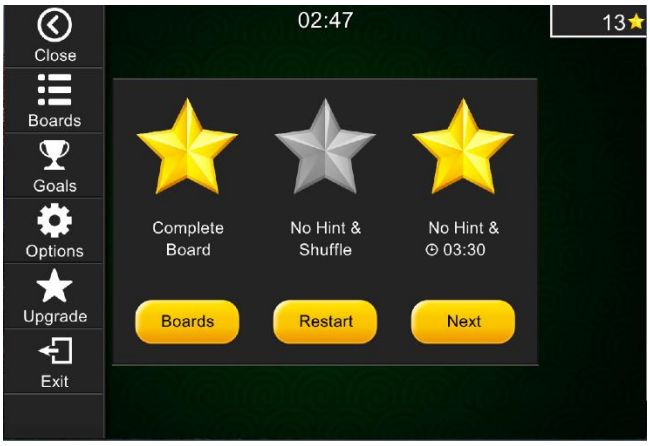
(2) Standard Operating Procedures for Mahjong Game

1. Open Mahjong Game via icon on desktop 

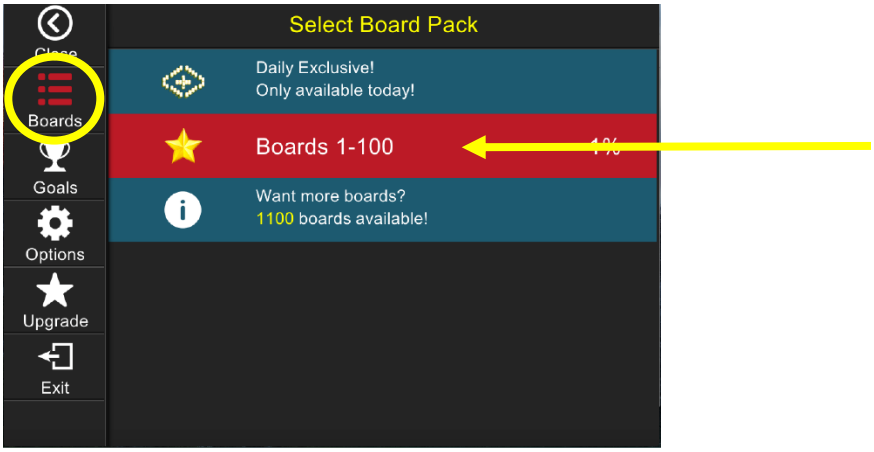
2. Show participant game instructions (see below) and allow them to ask questions. The goal is for them to be playing as close to continually as possible throughout the testing session, so they will be solving multiple puzzles.
3. After each session, you must manually record the data for the participant, as it will be OVERWRITTEN by each subsequent subject.

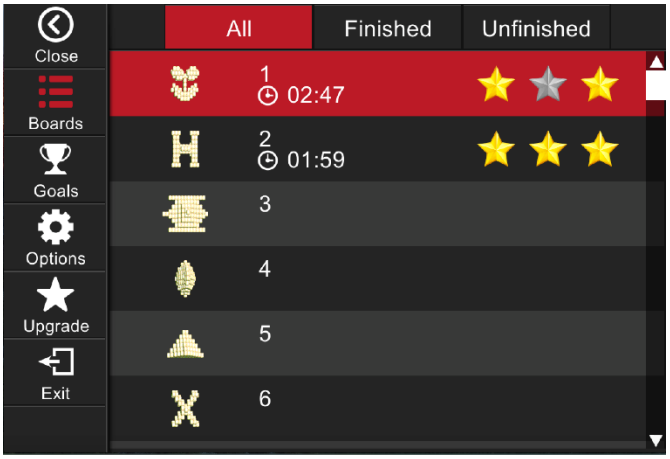


This “HOME” button is always visible during gameplay. Select the HOME icon to find the MAIN MENU.



Select the BOARDS icon to find the time statistics.



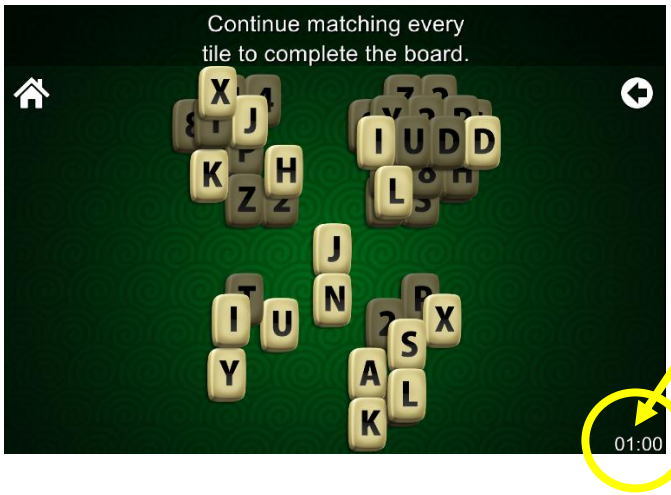


NOTE: The last game that had been played will be highlighted in RED on the BOARDS screen.

NOTE: If the board being worked on was INCOMPLETE when the experiment was stopped (either due to patient discomfort or 15 minute session completion) the time WILL NOT be recorded on the BOARDS screen.

- This is irrelevant if the patient reached 15 minutes.

There is a clock on the lower right hand corner of the screen. NOTE THE TIME when the participant stops the experiment and WRITE IT DOWN.



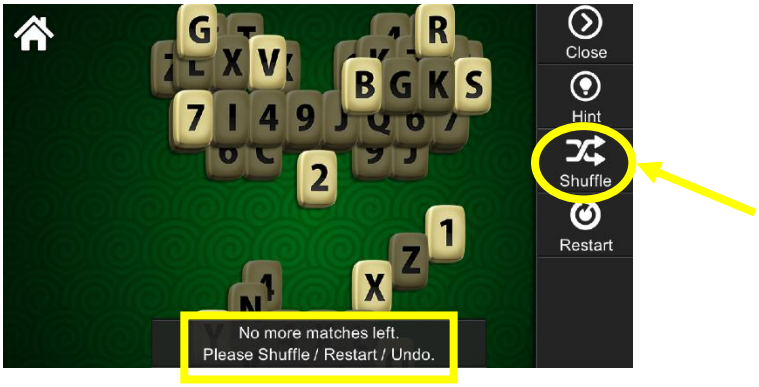
(3) Instructions for playing Mahjong

Mahjong is a matching game, using tiles with letters and numbers.

The goal is to find matching lit up tiles, then click them both to remove them.

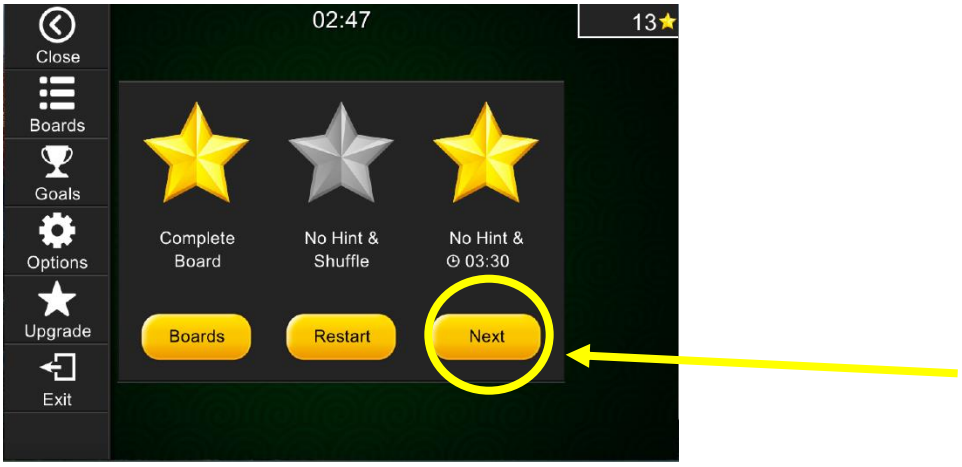
As matching tiles are eliminated, new tiles will light up. The goal is to remove all the tiles in the quickest amount of time.

Occasionally there will be no pairs of matching tiles available. Then you must select shuffle to continue.



After you have completed one set of tiles, you should continue with a new board.

We will want to you to play A DIFFERENT board every time. Your times to completion will be recorded for this experiment.



If you find that your eyes are straining more than what you would consider "barely tolerable" Please stop and tell the researcher AT ANY TIME.

If you are not having any eyestrain symptoms, you will play the game continuously for 15 minutes. The researcher will stop you at the conclusion of the session.

Appendix 4 – Operating Procedures for GoPro Hero 4 Silver Edition

Equipment:

1 GoPro Hero 4 Silver Edition Camera

1 Case/Stand

2 Batteries

2 64GB SanDisk Extreme PLUS Micro SD Cards

1 SanDisk Micro SD Adapter

2 USB Cables

1 Wall Charger

Settings:

Video Mode

30 FPS

1080 Video Resolution

Narrow FOV

<u>Instructions - Using the Camera During Testing:</u>

1. Power on: Press front **Power/Mode** button once. The camera status lights will flash red three times and emit 3 beeps. The screen will display information, indicating that the camera is on.

2. Confirm settings: Look on the bottom left of the back screen. Setting should read: **1080 / 30 / Narrow**.
    a. If the settings are incorrect: press the settings button on the right side of the camera. Scroll through the settings options until the settings listed above are chosen.

3. Position camera on tripod **22cm** from subject's left eye. Ensure the participants LEFT eye is centered in the camera view when the participant is positioned properly with the bite bar.
4. Take photograph of eye in looking at distance target.
    a. Swipe LEFT on the touchscreen to open the options screen

    b. Select Single
    c. Press the top **Shutter/Select** button once. The camera will beep two times and the lights will flash. The counter on the camera status screen will increase by one.
        i. NOTE: When the camera is in the case on the stand, this button (on the TOP of the camera) is covered with a silver button.

5. When ready to start the experiment video recording:
    a. Swipe LEFT on the touchscreen to open the options screen
    b. Select Video

    c. Visually confirm the settings on the bottom left of the back screen. Setting should read:

    1080 / 30 / Narrow. If it does not, return to step 2.

    d. Press the top **Shutter/Select** button once (see image above). The camera will beep once and the lights will flash while the camera is recording.

    e. Before commencing the experiment: STATE ALOUD

        i. Participant Number

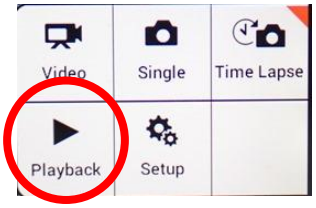
        ii. Condition (e.g. Baseline at distance, baseline at near, induction technique, or post testing)

6. To stop recording: Press the **Shutter/Select** button (see step 4c) once. The lights will flash three times and beep three times.
7. Repeat steps 4-6 for each testing condition.
8. Power off: Press and hold **Power/Mode** button (see step 1) for 2 seconds. The lights will flash red and beep seven times. The screen will go black.

<u>Instructions – Retrieving Video Data onto Computer:</u>

1. This should be performed after each participant has completed their visit.
2. Connect camera to computer via USB cable.

3. Copy files to computer:
    a. Study Folder
    b. Subject Number Folder
    c. Video file saved with this format: **STUDY_SUBJECT NUMBER_INDUCTION TECHNIQUE_DATE**
4. Content can be played back using the GoPro software (downloaded onto the laptops) or via playback option on the camera itself (see below, before deleting with Trashcan icon).
    a. Confirm quality of video recording.
5. Video files should be deleted off the camera once the file transfer is complete.
    a. Swipe LEFT on the touchscreen to open the options screen
    b. Select Playback
    c. Select the Video file you wish to delete
    d. Press the Trashcan icon to delete



    e. To return to the video screen, select the Squares icon (bottom right) and then the Exit icon (top right)
6. Turn off camera once data transfer is complete (see instructions above).

Instructions – Charging the Camera:

1. After EACH USE the camera should be returned to the charging station, as the battery life is 2 hours.
2. Connect the camera via USB cable (see above) to the wall charger. Plug in for 2 hours for a complete charge.
3. Remember to lock up the unit in the cabinet at the end of the day. If the charge was not complete, at the beginning of the day, connect the charger before subjects arrive.

Appendix 5 – Font Size Conversion

Mathematical conversion of 5 point Verdana font at 60cm working distance to Mahjong Solitaire Epic tile image height imaged to iPhone at 40cm working distance:

5 point Verdana font is measured at a standard 1.8797mm.[116]

Equation: $\tan(5/60) = h/6$

5 point font at 60cm: $\tan(x/60) = (1.8797_E{}^{-3}/0.6m)$

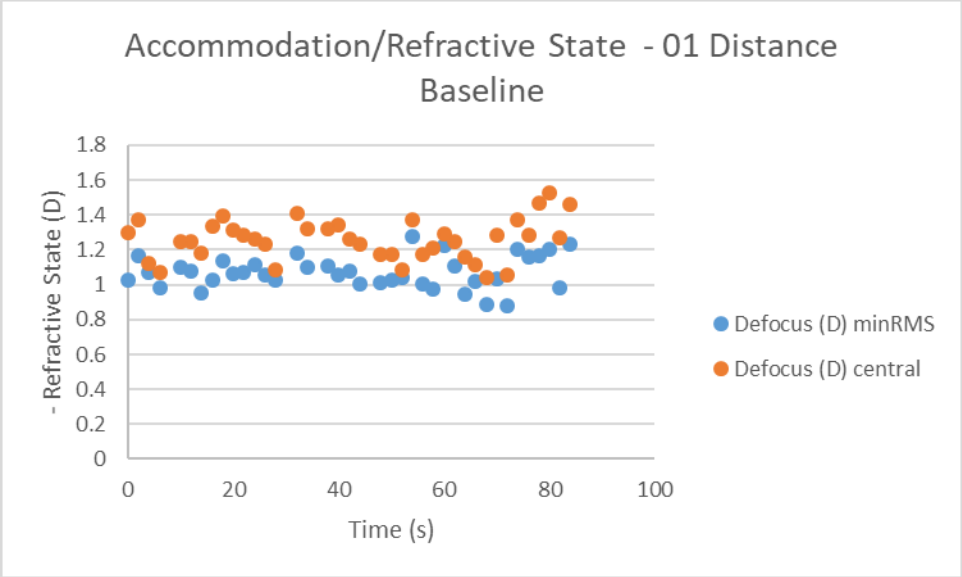
$x = 10.76584178'$

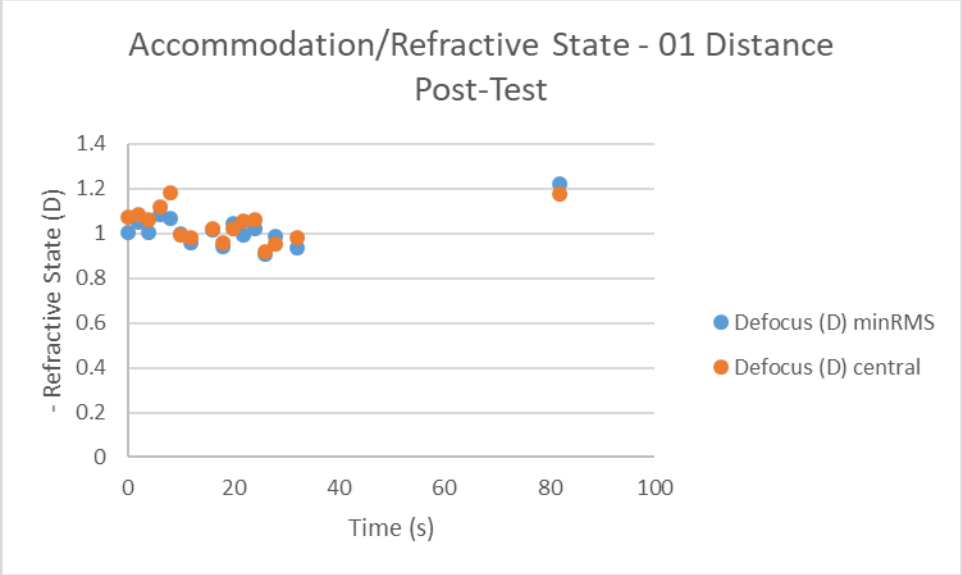
mm height required at 40cm: $\tan(10.76584178/60) = h/0.4m$

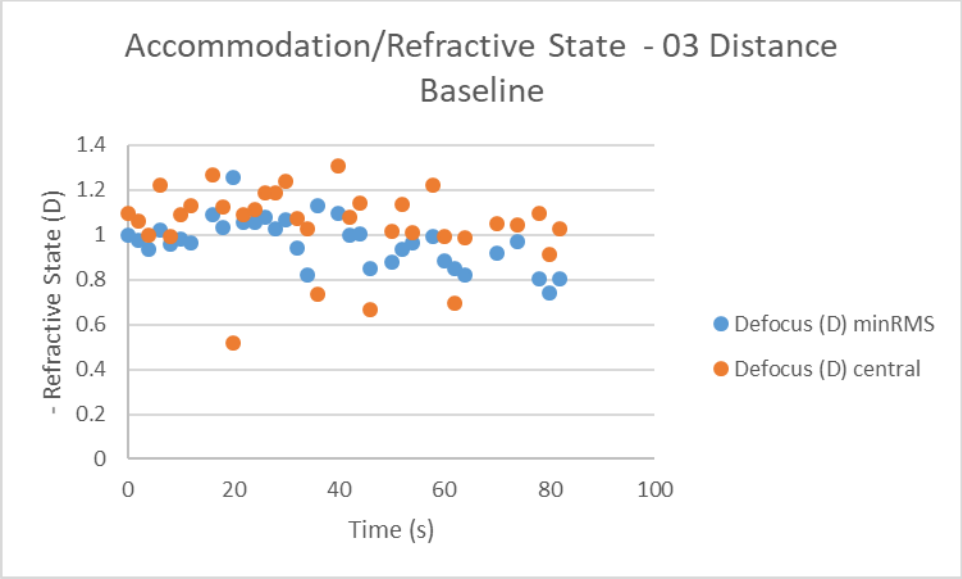
$h = 0.001252667m = 1.2526mm$

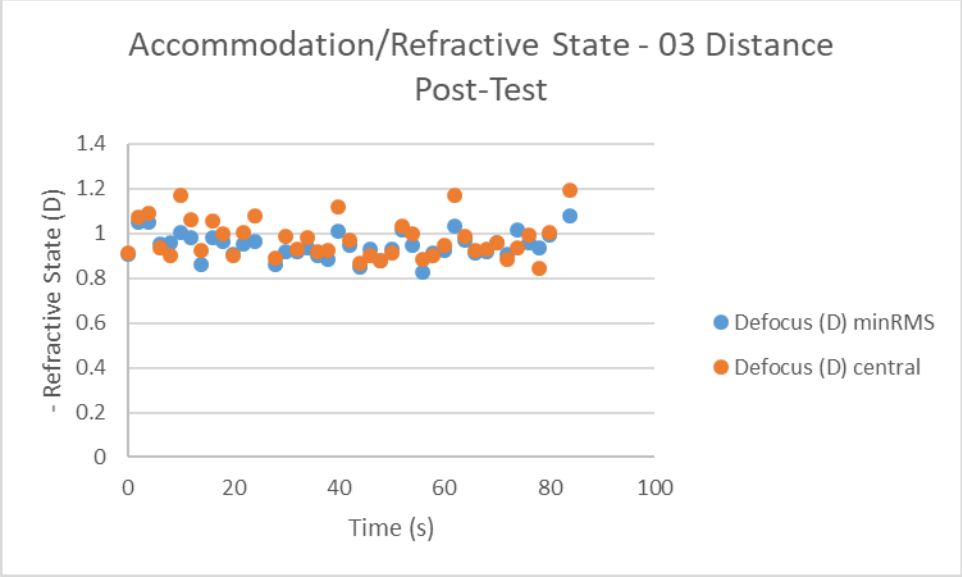
[116] Font Size Conversion. Available at: http://unitarium.com/font. Accessed June 23, 2015.

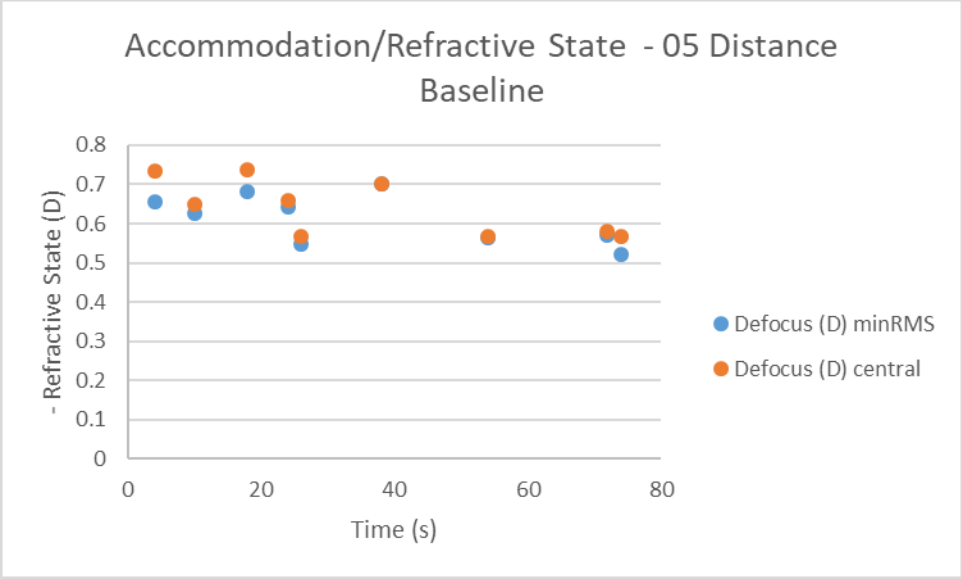
Appendix 6 – Distance Pre-Test and Post-Test Graphs

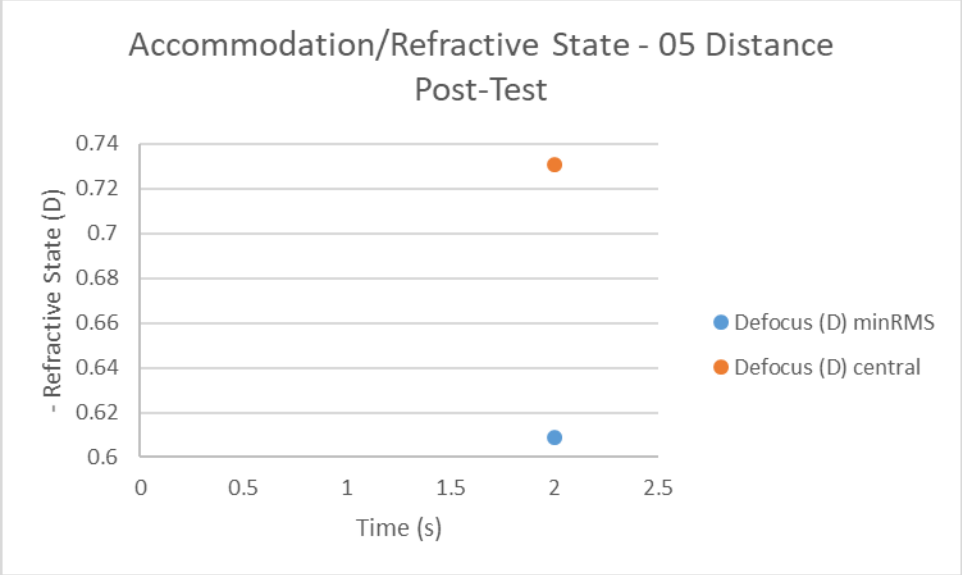


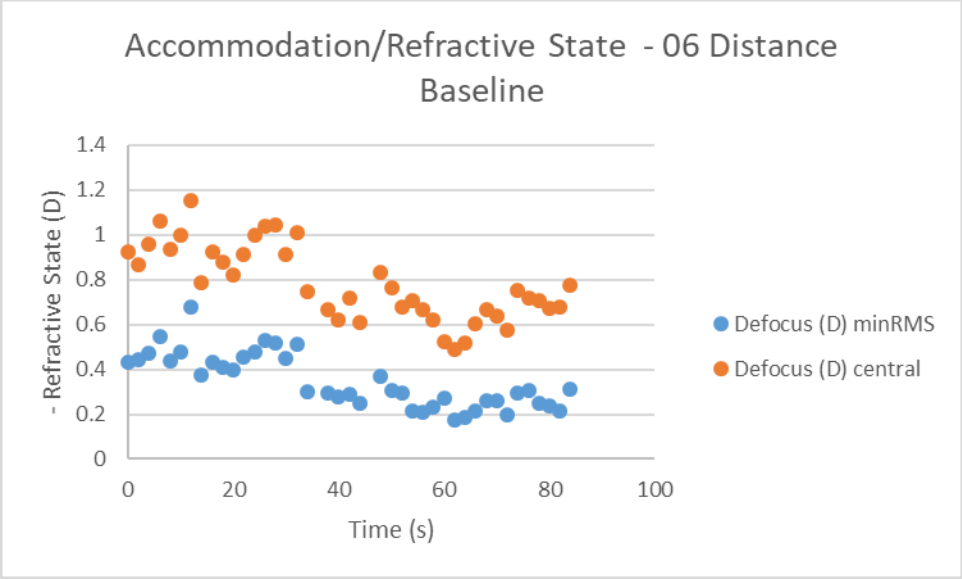


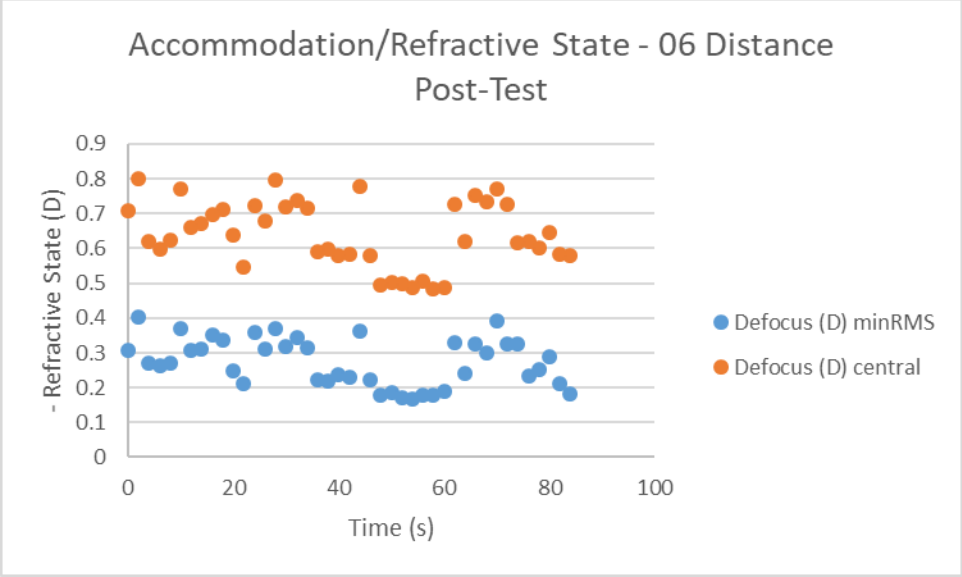

Accommodation/Refractive State - 03 Distance Baseline
- Refractive State (D)
1.4
1.2
1
0.8
0.6
0.4
0.2
0
0
20
40
60
80
100
Time (s)
Defocus (D) minRMS
Defocus (D) central

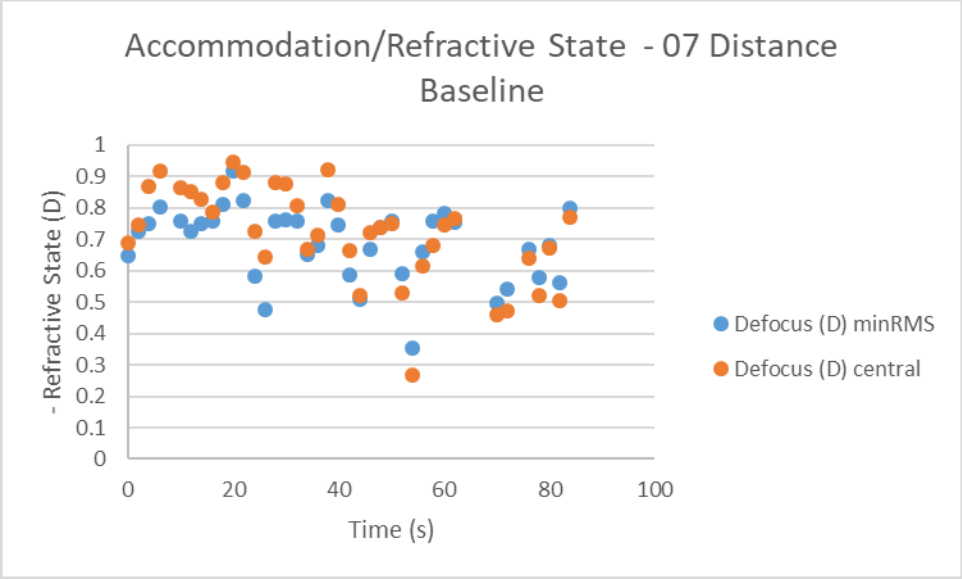

Accommodation/Refractive State - 03 Distance Post-Test
- Refractive State (D)
1.4
1.2
1
0.8
0.6
0.4
0.2
0
0
20
40
60
80
100
Time (s)
Defocus (D) minRMS
Defocus (D) central

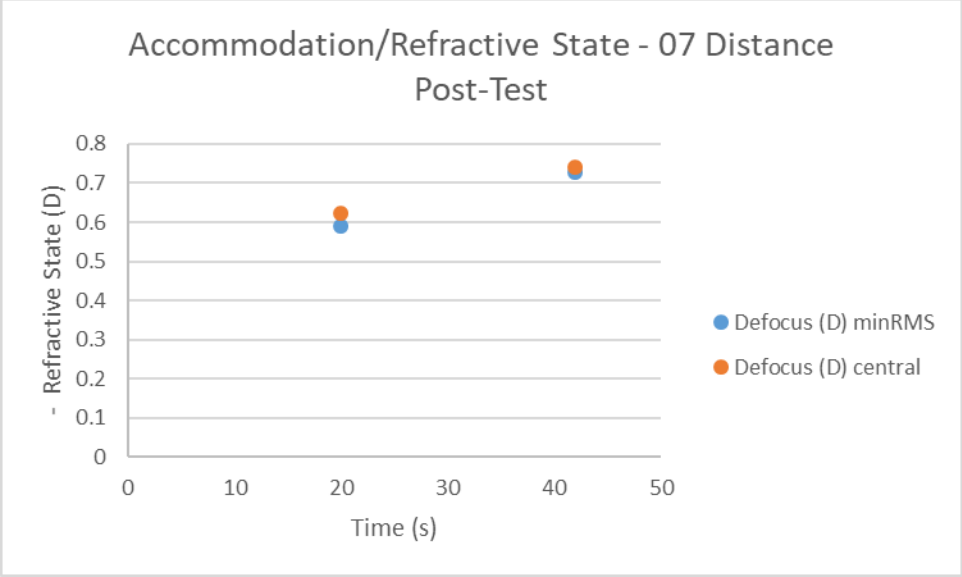

Accommodation/Refractive State - 05 Distance Baseline
- Refractive State (D)
0.8
0.7
0.6
0.5
0.4
0.3
0.2
0.1
0
0
20
40
60
80
Time (s)
Defocus (D) minRMS
Defocus (D) central

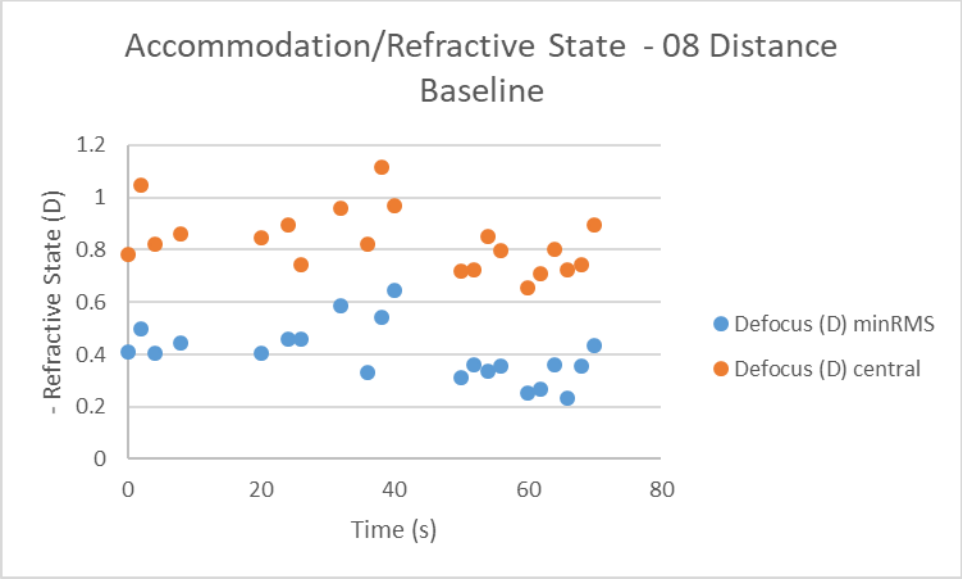

Accommodation/Refractive State - 05 Distance Post-Test
- Refractive State (D)
0.74
0.72
0.7
0.68
0.66
0.64
0.62
0.6
0
0.5
1
1.5
2
2.5
Time (s)
Defocus (D) minRMS
Defocus (D) central

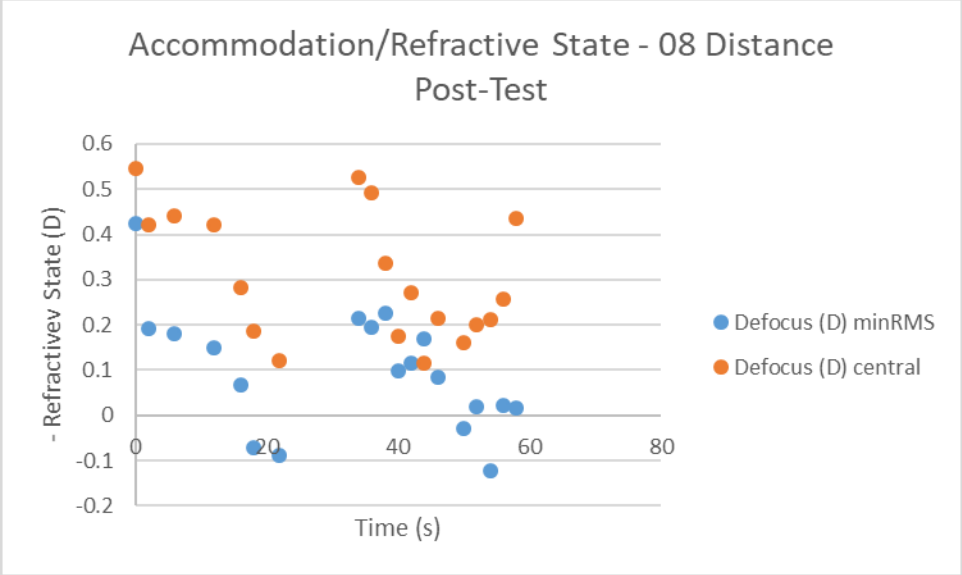

Accommodation/Refractive State - 06 Distance Baseline
- Refractive State (D)
1.4
1.2
1
0.8
0.6
0.4
0.2
0
0
20
40
60
80
100
Time (s)
Defocus (D) minRMS
Defocus (D) central

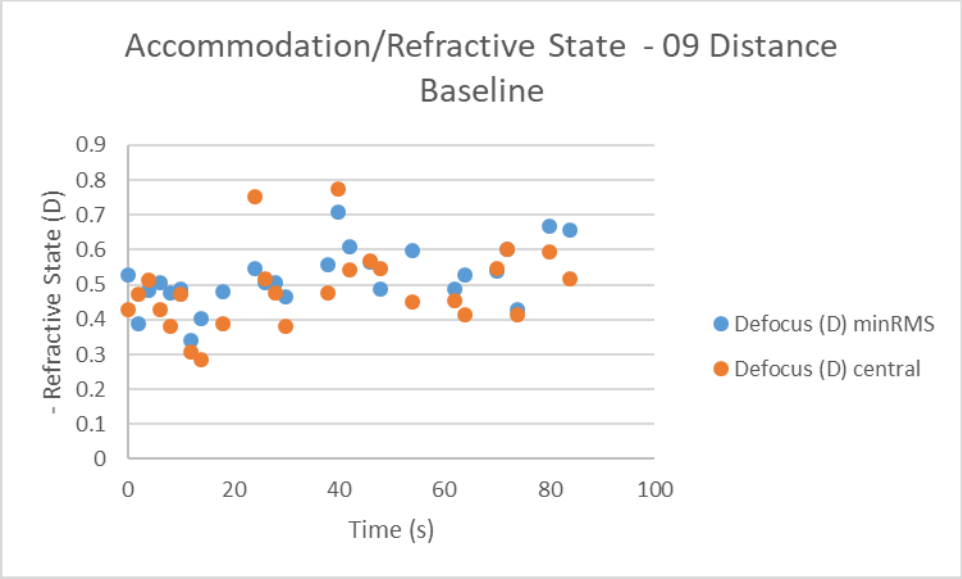

Accommodation/Refractive State - 06 Distance Post-Test
- Refractive State (D)
0.9
0.8
0.7
0.6
0.5
0.4
0.3
0.2
0.1
0
0
20
40
60
80
100
Time (s)
Defocus (D) minRMS
Defocus (D) central

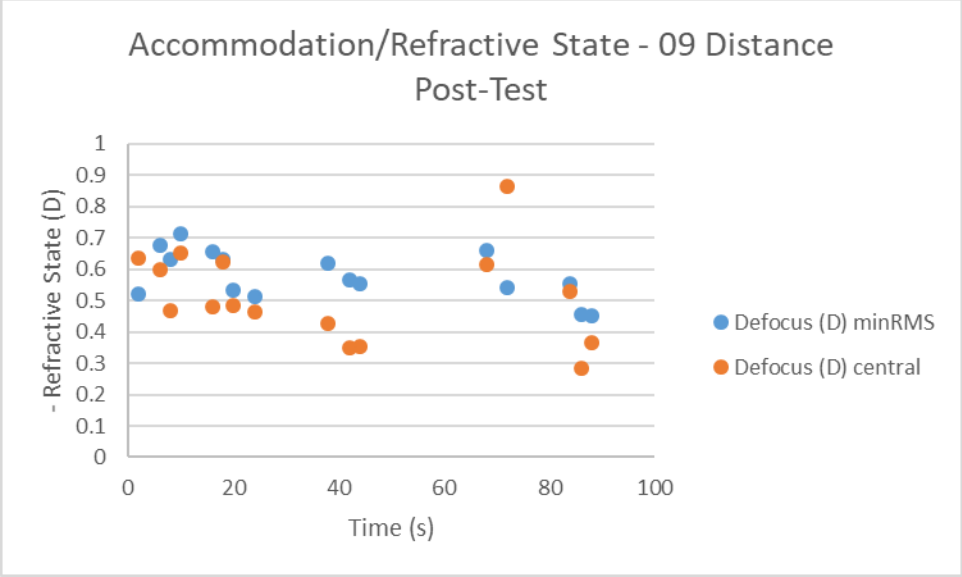

Accommodation/Refractive State - 07 Distance Baseline
- Refractive State (D)
1
0.9
0.8
0.7
0.6
0.5
0.4
0.3
0.2
0.1
0
0
20
40
60
80
100
Time (s)
Defocus (D) minRMS
Defocus (D) central

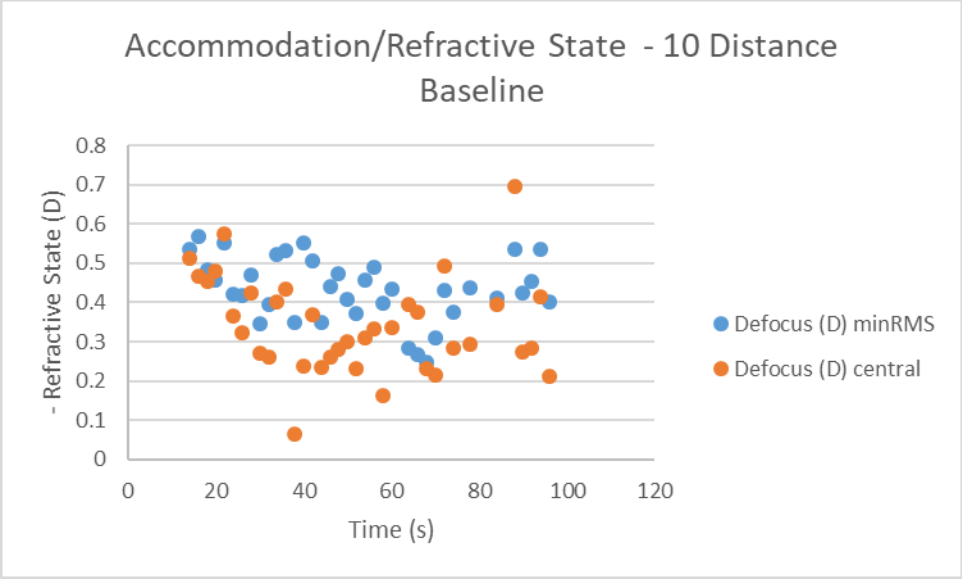

Accommodation/Refractive State - 07 Distance Post-Test
- Refractive State (D)
0.8
0.7
0.6
0.5
0.4
0.3
0.2
0.1
0
0
10
20
30
40
50
Time (s)
Defocus (D) minRMS
Defocus (D) central

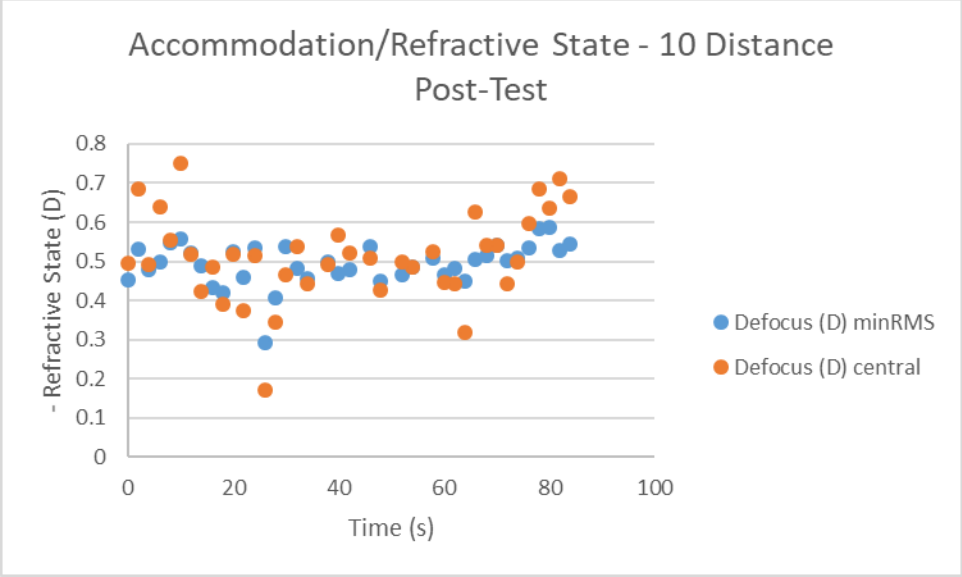

Accommodation/Refractive State - 08 Distance Baseline
- Refractive State (D)
1.2
1
0.8
0.6
0.4
0.2
0
0
20
40
60
80
Time (s)
Defocus (D) minRMS
Defocus (D) central


Accommodation/Refractive State - 08 Distance Post-Test
- Refractivev State (D)
0.6
0.5
0.4
0.3
0.2
0.1
0
-0.1
-0.2
0
20
40
60
80
Time (s)
Defocus (D) minRMS
Defocus (D) central

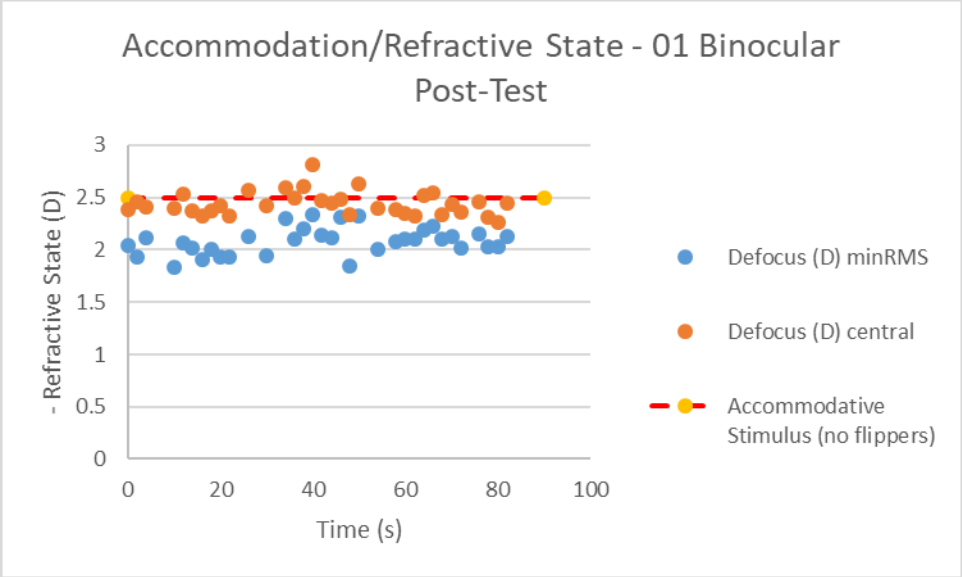

Accommodation/Refractive State - 09 Distance Baseline
- Refractive State (D)
0.9
0.8
0.7
0.6
0.5
0.4
0.3
0.2
0.1
0
0
20
40
60
80
100
Time (s)
Defocus (D) minRMS
Defocus (D) central

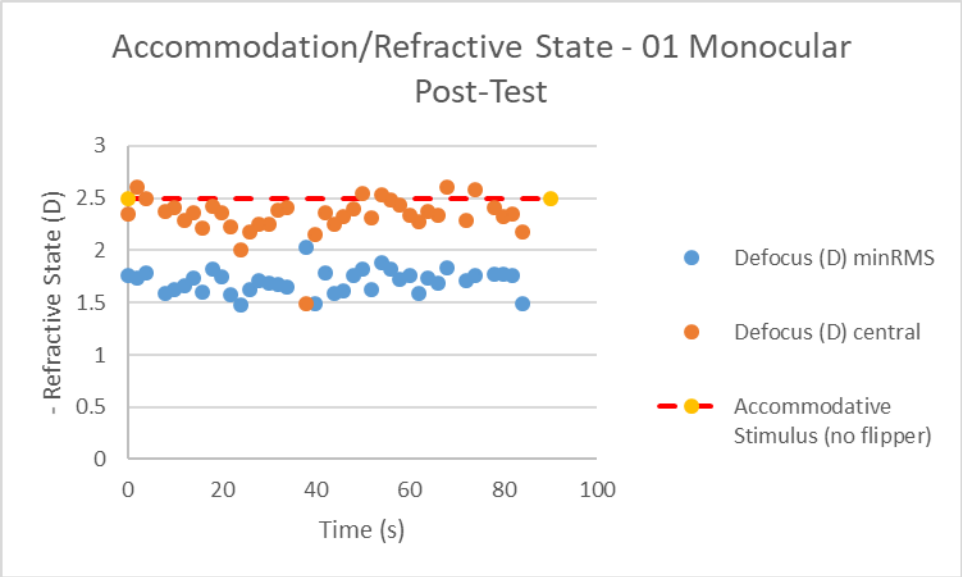

Accommodation/Refractive State - 09 Distance Post-Test
- Refractive State (D)
1
0.9
0.8
0.7
0.6
0.5
0.4
0.3
0.2
0.1
0
0
20
40
60
80
100
Time (s)
Defocus (D) minRMS
Defocus (D) central

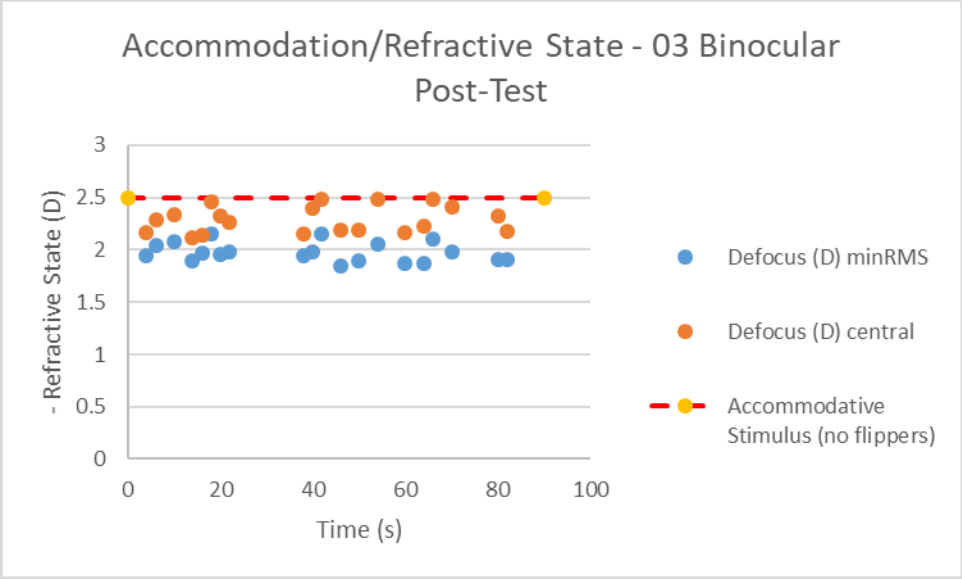

Accommodation/Refractive State - 10 Distance Baseline
- Refractive State (D)
0.8
0.7
0.6
0.5
0.4
0.3
0.2
0.1
0
0
20
40
60
80
100
120
Time (s)
Defocus (D) minRMS
Defocus (D) central

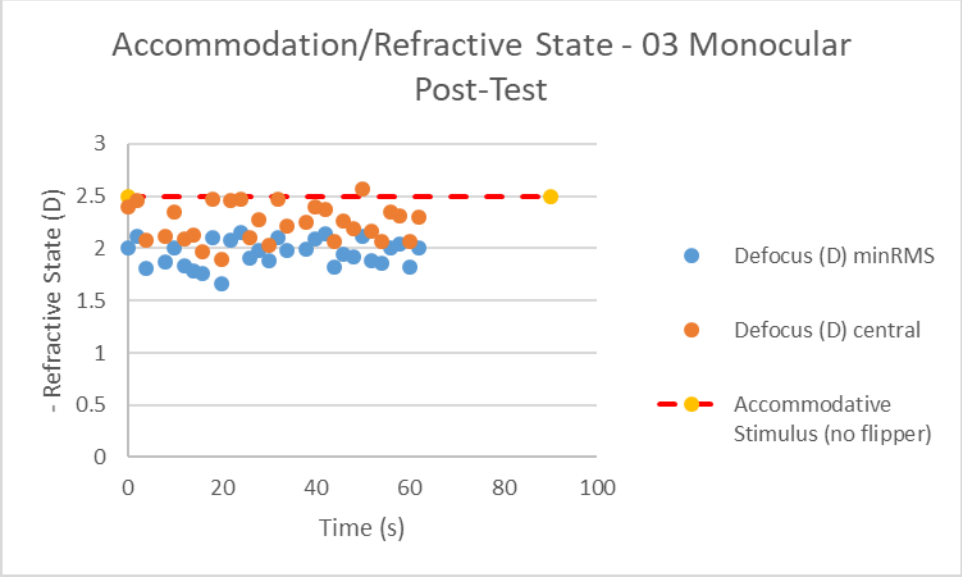

Accommodation/Refractive State - 10 Distance Post-Test
- Refractive State (D)
0.8
0.7
0.6
0.5
0.4
0.3
0.2
0.1
0
0
20
40
60
80
100
Time (s)
Defocus (D) minRMS
Defocus (D) central

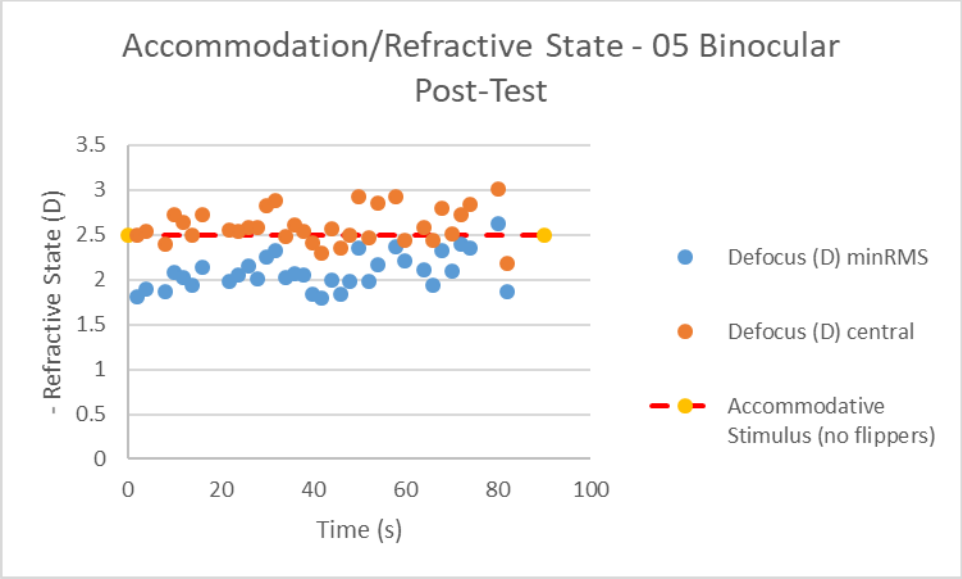
Appendix 7 – Binocular and Monocular Post-Test Graphs

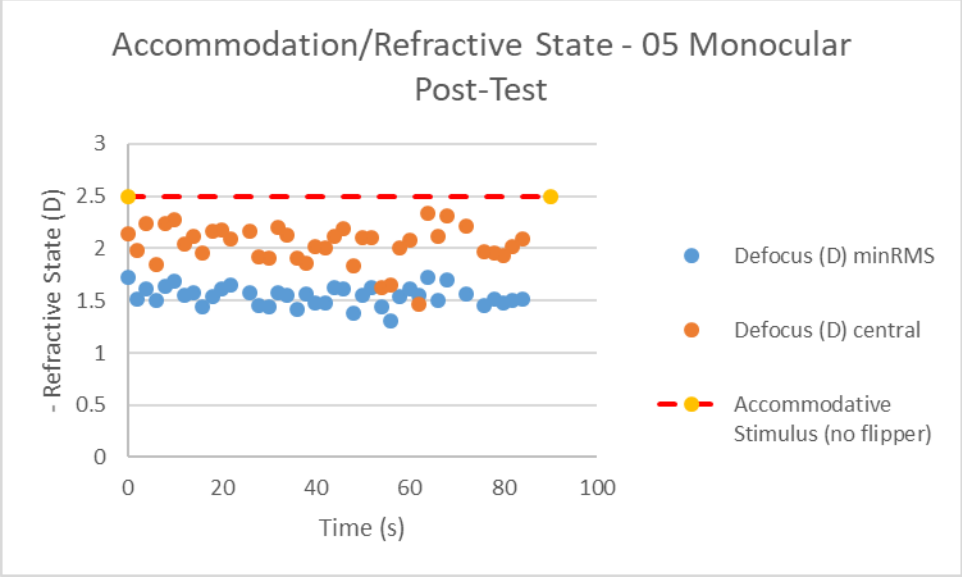


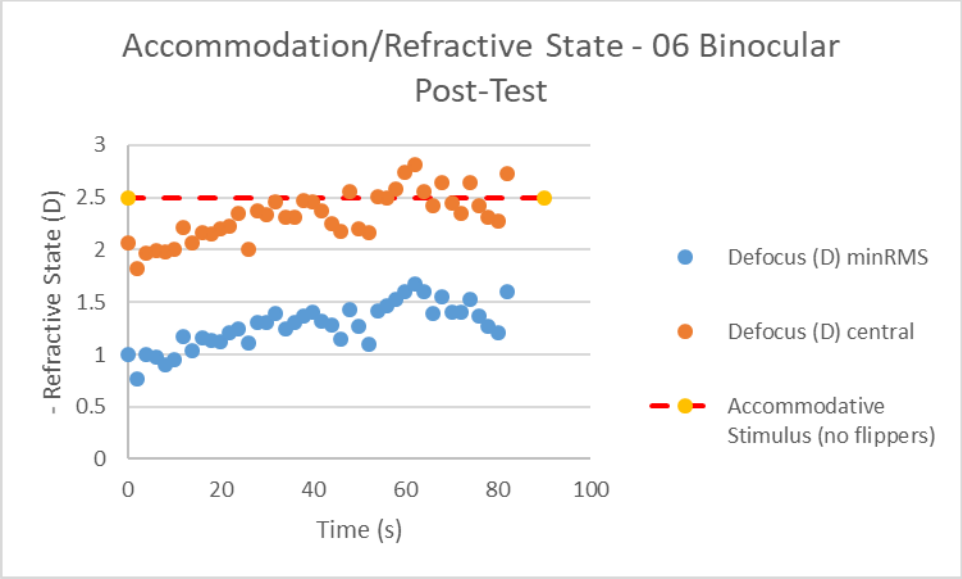


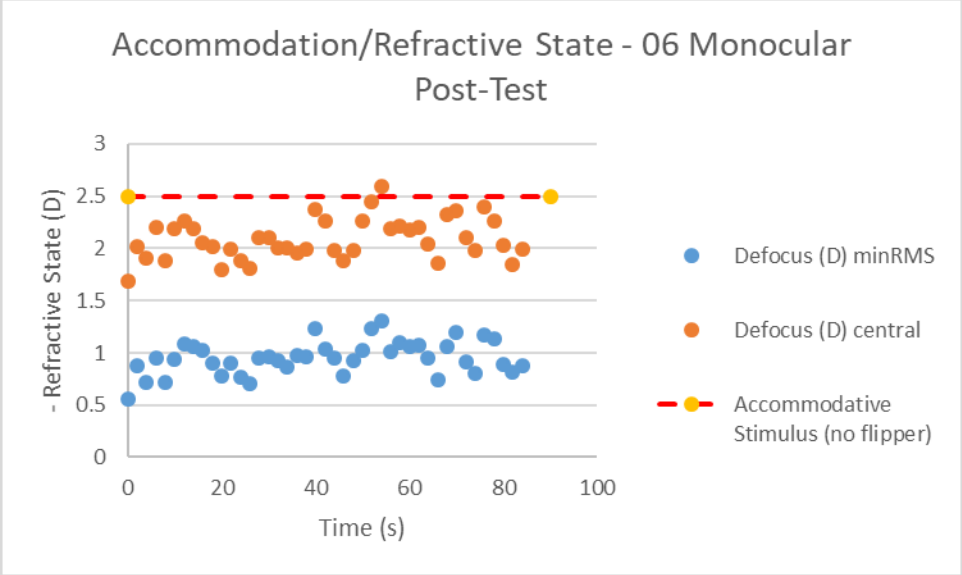

Accommodation/Refractive State - 03 Binocular Post-Test
- Refractive State (D)
3
2.5
2
1.5
1
0.5
0
0
20
40
60
80
100
Time (s)
Defocus (D) minRMS
Defocus (D) central
Accommodative Stimulus (no flippers)

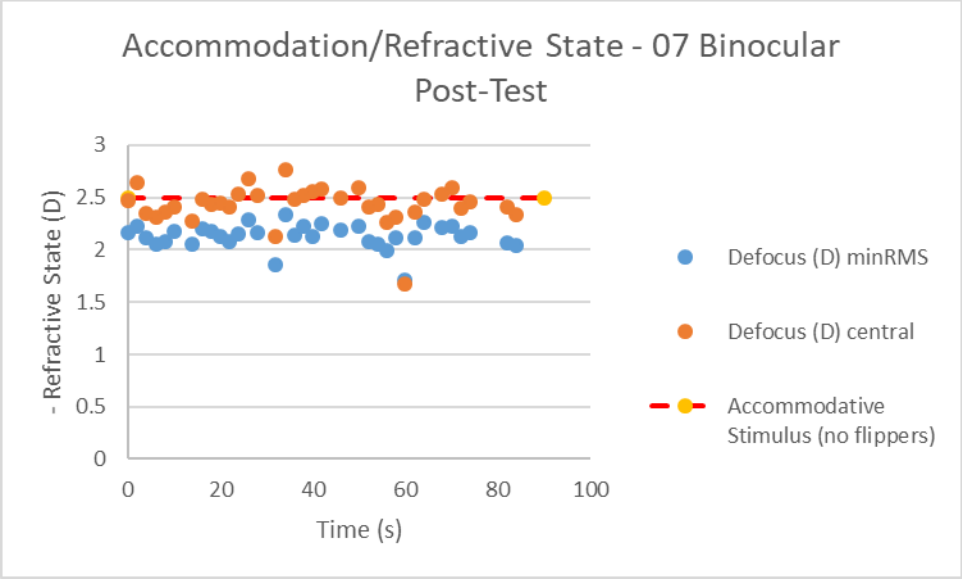

Accommodation/Refractive State - 03 Monocular Post-Test
- Refractive State (D)
3
2.5
2
1.5
1
0.5
0
0
20
40
60
80
100
Time (s)
Defocus (D) minRMS
Defocus (D) central
Accommodative Stimulus (no flipper)

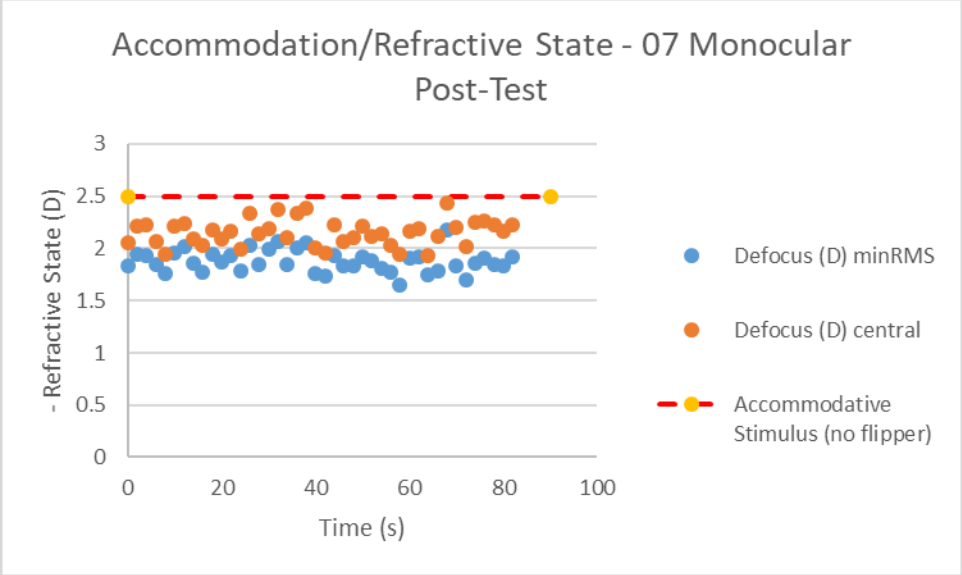

Accommodation/Refractive State - 05 Binocular Post-Test
- Refractive State (D)
3.5
3
2.5
2
1.5
1
0.5
0
0
20
40
60
80
100
Time (s)
Defocus (D) minRMS
Defocus (D) central
Accommodative Stimulus (no flippers)

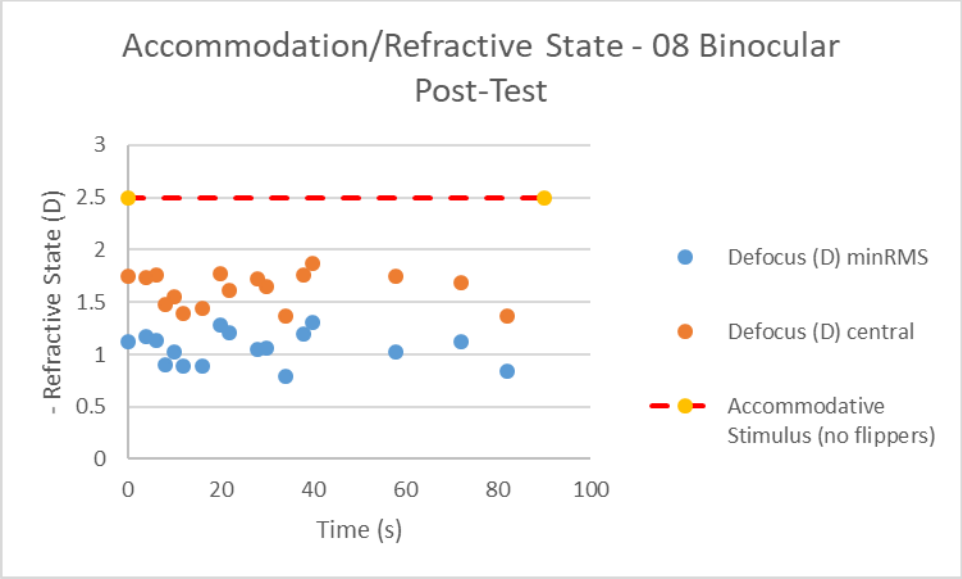

Accommodation/Refractive State - 05 Monocular Post-Test
- Refractive State (D)
3
2.5
2
1.5
1
0.5
0
0
20
40
60
80
100
Time (s)
Defocus (D) minRMS
Defocus (D) central
Accommodative Stimulus (no flipper)

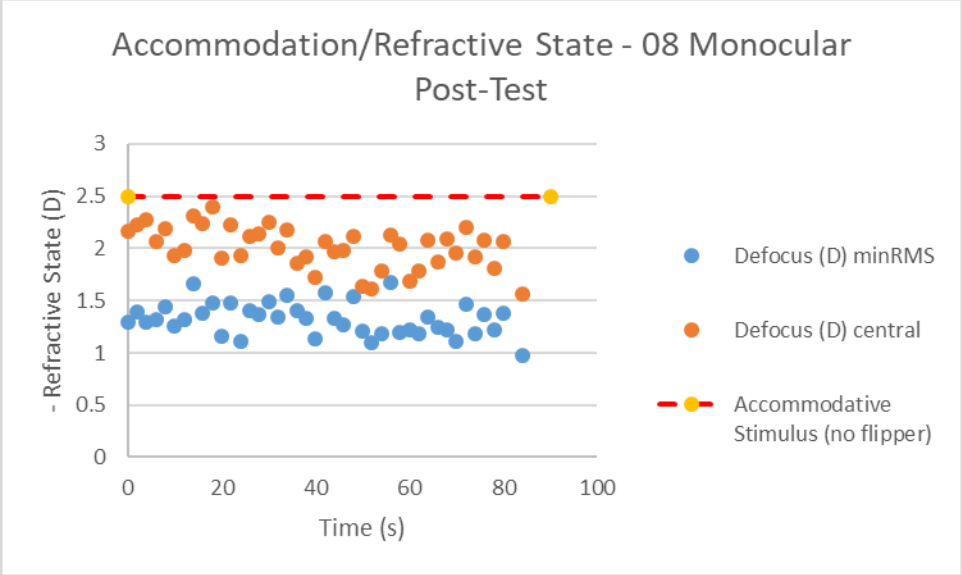

Accommodation/Refractive State - 06 Binocular Post-Test
- Refractive State (D)
3
2.5
2
1.5
1
0.5
0
0
20
40
60
80
100
Time (s)
Defocus (D) minRMS
Defocus (D) central
Accommodative Stimulus (no flippers)

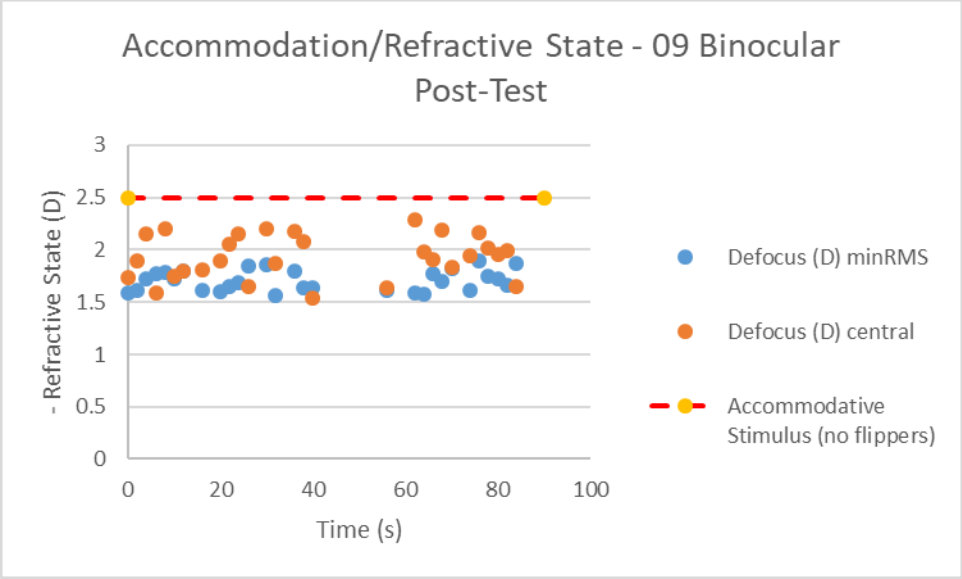

Accommodation/Refractive State - 06 Monocular Post-Test
- Refractive State (D)
3
2.5
2
1.5
1
0.5
0
0
20
40
60
80
100
Time (s)
Defocus (D) minRMS
Defocus (D) central
Accommodative Stimulus (no flipper)

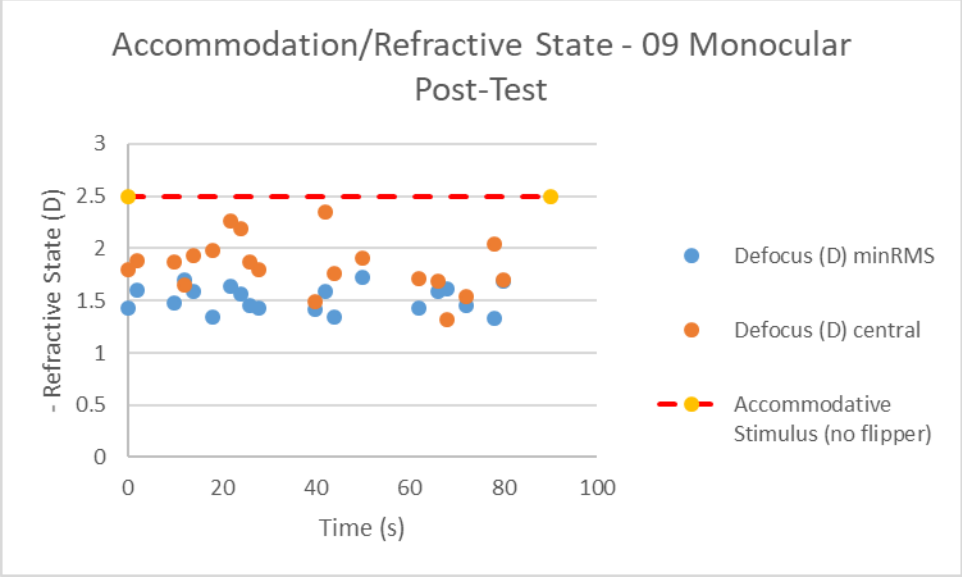

Accommodation/Refractive State - 07 Binocular Post-Test
- Refractive State (D)
3
2.5
2
1.5
1
0.5
0
0
20
40
60
80
100
Time (s)
Defocus (D) minRMS
Defocus (D) central
Accommodative Stimulus (no flippers)

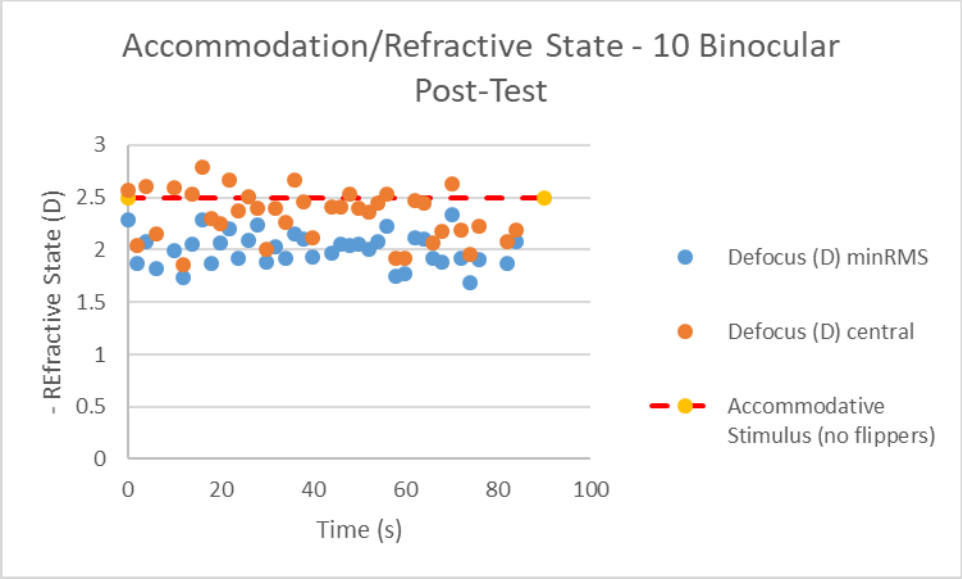

Accommodation/Refractive State - 07 Monocular Post-Test
- Refractive State (D)
3
2.5
2
1.5
1
0.5
0
0
20
40
60
80
100
Time (s)
Defocus (D) minRMS
Defocus (D) central
Accommodative Stimulus (no flipper)

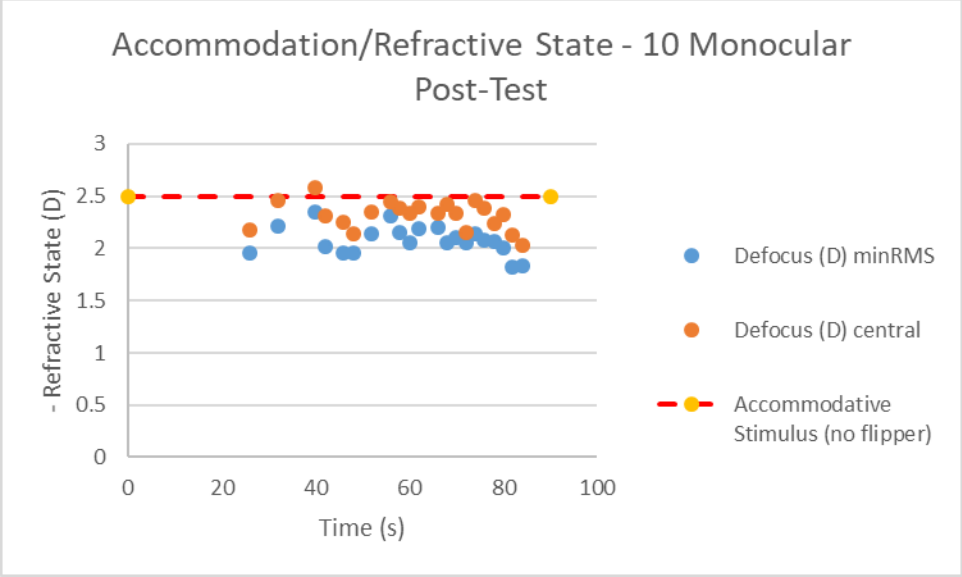

Accommodation/Refractive State - 08 Binocular Post-Test
- Refractive State (D)
3
2.5
2
1.5
1
0.5
0
0
20
40
60
80
100
Time (s)
Defocus (D) minRMS
Defocus (D) central
Accommodative Stimulus (no flippers)


Accommodation/Refractive State - 08 Monocular Post-Test
- Refractive State (D)
3
2.5
2
1.5
1
0.5
0
0
20
40
60
80
100
Time (s)
Defocus (D) minRMS
Defocus (D) central
Accommodative Stimulus (no flipper)


Accommodation/Refractive State - 09 Binocular Post-Test
- Refractive State (D)
3
2.5
2
1.5
1
0.5
0
0
20
40
60
80
100
Time (s)
Defocus (D) minRMS
Defocus (D) central
Accommodative Stimulus (no flippers)


Accommodation/Refractive State - 09 Monocular Post-Test
- Refractive State (D)
3
2.5
2
1.5
1
0.5
0
0
20
40
60
80
100
Time (s)
Defocus (D) minRMS
Defocus (D) central
Accommodative Stimulus (no flipper)


Accommodation/Refractive State - 10 Binocular Post-Test
- REfractive State (D)
3
2.5
2
1.5
1
0.5
0
0
20
40
60
80
100
Time (s)
Defocus (D) minRMS
Defocus (D) central
Accommodative Stimulus (no flippers)


Accommodation/Refractive State - 10 Monocular Post-Test
- Refractive State (D)
3
2.5
2
1.5
1
0.5
0
0
20
40
60
80
100
Time (s)
Defocus (D) minRMS
Defocus (D) central
Accommodative Stimulus (no flipper)

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(née Figueira)

smhuenink@gmail.com

EDUCATION

Indiana University School of Optometry — **Bloomington, IN**
Doctor of Optometry — May, 2016
Master of Science in Vision Science — December, 2019

University of Wisconsin-Milwaukee – Peck School of the Arts — **Milwaukee, WI**
Bachelor of Fine Arts in Clarinet Performance — May, 2012
Minor in Biology — May, 2012

GRADUATE PROGRAM AWARDS

Recipient of the David H. Kolack, O.D. Award for the student with the highest GPA at the end of seven semesters of optometry school (2016)

Recipient of the Beta Sigma Kappa Silver Medal Award for the graduating student with the highest GPA who is a current BSK member (2016)

Recipient of the Jack Bennett Endowed Scholarship for a third year student in good standing, selected by the Awards & Honors Committee (2016)

Recipient of the Vistakon 2016 Award of Excellence in Contact Lens Patient Care (2016)

Recipient of E.F. Wildermuth Foundation / Harriet Slaughter Scholarship for the student with the highest GPA at the end of the first semester, third year (2015)

Participant in the Dean's Summer Scholars Research Program sponsored by National Eye Institute (2013)

Recipient of a renewable Faculty Fellowship Award (2012, 2013, 2014, 2015, 2016)

PROFESSIONAL ORGANIZATIONS

Member of the American Optometric Association
Member of the Wisconsin Optometric Association
Member of Vision Source

CONFERENCE PRESENTATIONS

D. Meyer, S. Huenink, M. Rickert, P. Chamberlain, P. Kollbaum; October 8, 2015; Symptoms associated with eye fatigue in soft contact lens wearers; American Academy of Optometry Annual Meeting; New Orleans, LA

P. Kollbaum, S. Huenink, R. McGiffen, M. Rickert, J. Tarrant, P. Chamberlain; May 6, 2014; A Best-Eye Model of Binocular Summation with Presbyopic Contact Lens Corrections; Association for Research in Vision and Ophthalmology Annual Meeting; Orlando, FL

S. Figueira, L. Hopkins, E. Browning, P. Heffernan, O. Kattan, M. Schwartz, and A.J. Greene; April 20, 2012; Auditory Transitive Inference; UW-Milwaukee Undergraduate Research Symposium; Milwaukee, WI

P. Leo, L. Hopkins, E. Browning, P. Heffernan, A. Hinman, S. Figueira, K. Balling, O. Kattan, and A.J. Greene; April 2, 2012; The hippocampus in inference: Distinct hippocampal activation for implicit versus explicit performance; Cognitive Neuroscience Society Meeting; Chicago, IL

S. Figueira, L. Hopkins, A.J. Greene; April 22, 2011; Auditory Inference; UW-Milwaukee Undergraduate Research Symposium; Milwaukee, WI

RESEARCH EXPERIENCE

Clinical Optics Research Laboratory, Indiana University School of Optometry, Bloomington, IN
January 2013-July 2016
Research Assistant
Supervisors: Pete Kollbaum, O.D., Ph.D. FAAO, FBCLA; Dawn Meyer, O.D.

Greene Cognitive Neuroscience Laboratory, University of Wisconsin-Milwaukee, Milwaukee, WI
September 2010-May 2012
Research Assistant
Supervisor: Anthony J. Greene, Ph.D.

TEACHING EXPERIENCE

Indiana University School of Optometry, Bloomington, IN
August 2013-May 2015
Assistant Instructor – Geometric Optics
Supervisors: Nikole L. Himebaugh, O.D., Ph.D.; Clifford W. Brooks, O.D.

PROFESSIONAL EXPERIENCE

Koskinen Eye Clinic, East Troy, WI
July 2016-Present
Optometrist

Bascom Palmer Eye Institute, Miami, FL
November 2015-April 2016
Optometry Extern – Winter and Spring Combined Rotation

Vision Care Specialists, Des Plaines, IL
August 2015-October 2015
Optometry Extern – Autumn Rotation

Atwater Eyecare Center, Bloomington, IN
May 2015-July 2015
Optometry Intern – Summer Rotation

Vision Heath Eyecare Center, Cudahy, WI
May 2011-July 2012
Optometric Technician